DECLARATION OF JEROME P. SKELLY, PH.D.

I, JEROME P. SKELLY, Ph.D., have been retained as an expert on behalf of King Pharmaceuticals, Inc. ("King"). I have been asked to assess the pharmacokinetic results of certain clinical studies[1] conducted in connection with the muscle relaxant drug product, Skelaxin® (metaxalone). In particular, I have been asked to opine on the importance of including such results in the labeling for generic versions of Skelaxin®. I have also been asked provide comments on the submissions made to the United States Food and Drug Administration ("FDA") on behalf of CorePharma LLC ("Core"), including the Declaration of Paul Bass ("Bass Declaration"), and Mutual Pharmaceutical Co., Inc. ("Mutual").

I. STATEMENT OF QUALIFICATIONS

1. I received my undergraduate degree and my Ph.D. in Chemistry from Wayne State University in Detroit, and completed a post-doctorate in Pharmaceutics at UCSF in San Francisco.

2. For more than 24 years, I held senior scientific and management positions in FDA. During much of that time period, I was Director and Program Manager for Biopharmaceutics. I was also a World Health Organization consultant to Egypt. At the time of my retirement, I was a member of the Federal Government's 'Senior Executive Service' holding joint appointments as Deputy Director of CDER's Office of Research and Associate Director (for Science) in OGD.

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[1] Although King recently acquired the Skelaxin® NDA and did not sponsor the clinical studies discussed in this declaration, for ease of reference, I will refer to them as King's studies.

3. I am President-Elect of the American Association of Pharmaceutical Scientists; Immediate Past Chairman of the Board of Directors of the Product Quality Research Institute [(PQRI), a consortium of AAPS, FDA, USP, Industry and other health interest groups and societies]; and Adjunct Professor of Biopharmaceutics at the College of Pharmacy, University of Cincinnati. I am also a Charter Member of FDA's Alumni Association. I am also a biopharmaceutical consultant, and I presently sit on the scientific and/or strategic advisory boards of several pharmaceutical firms.

4. I have made more than 250 scientific and policy presentations, and authored/co-authored more than 100 publications, in addition to editorials and a significant number of posters, monographs, abstracts, and guidelines. I am co-editor of books in the area of pharmacokinetics, pharmacodynamics, and toxicokinetics, and a member of the Editorial Boards of the Marcel Dekker Pharmaceutic Series, the Journal of Clinical Research and Regulatory Affairs, and the International Editorial Advisory Board of the 2'nd Edition of the Encyclopedia of Pharmaceutical Technology. I have also served on the Editorial Board of the Journal of Clinical Pharmacology.

5. I was twice given the Public Health Services "Equal Opportunity Award", several commendations in recognition for service to the public health, a "Commissioner's Special Citation" for work on the electronic submission of data (CANDA), and the FDA's highest award "The FDA Award of Merit" for my work in generic drug compliance and biopharmaceutics. I am the recipient of the 1996 AAiPS "Recognition Award" for playing a leading role in the globalization of quality standards and devoted service to the advancement of the pharmaceutical sciences; and the 2002 AAPS' "Distinguished Service Award" for contributions to AAPS.

6. I am a Fellow and Sustaining Member of AAPS, a Fellow of both the American College of Clinical Pharmacology and the American Association of Indian Pharmaceutical Scientists, and a member of both Phi Lambda Upsilon (Chemistry Honors Society) and the Research Society of America. I am a past Vice-Chair, Chair-Elect and Chair of the AAPS' Pharmacokinetics, Pharmacodynamics, & Drug Metabolism Section (PPDM) and was actively involved with the development and organization of PPDM's first 'Open Forum'. I have chaired the PPDM and Regulatory Science (RS) Section's Strategic Planning and Fellows Nomination' Committees, and represented PPDM on the Annual Meeting Committee. Additionally, I was the 1990-93 Elected Member at Large on AAPS' Executive Council and served on the RS Section's Executive Committee for eight years. I have also been a member of the AAPS' Governance and Fellows Task Forces, and served nine terms (once as 'Outside Reviewer' and three times as Chair) on the AAPS' Fellows Selection Committee.

7. I have been actively involved with many significant scientific activities including organizing, chairing, moderating, and speaking at numerous scientific symposia, short-courses, and workshops. As an FDA Senior Executive, I initiated the holding of public FDA workshops as a way of tackling and addressing complex scientific/regulatory problems in an open forum, and publishing the results -- among the more significant of these were the AAPS-FDA 'Scale-Up Workshops', which set the stage for SUPAC.

II. OVERVIEW OF OPINION

8. Based on my review of a March 1, 2004 letter from the FDA Office of Generic Drugs to Abbreviated New Drug Application ("ANDA") applicants for generic versions of metaxalone, it is my understanding that the FDA may be planning to permit the omission of the results of human studies demonstrating the increase in the bioavailability of metaxalone when co-

administered with food from the labeling for generic versions of Skelaxin®, in spite of the fact that this information properly appears in the labeling of Skelaxin®. It is also my understanding that a Skelaxin® labeling supplement proposing to including the results of additional clinical studies demonstrating the effect of age and gender on the bioavailability of metaxalone in both the fed state and the fasted state is currently pending before the FDA.

9. I am aware that King submitted a Citizen Petition to the FDA explaining why the omission of the results of the clinical studies from the labeling for generic metaxalone products would render those generic products less safe or effective than Skelaxin® for their remaining conditions of use. It is my understanding that Core and Mutual each submitted comments to the FDA supporting their efforts to carve out the pharmacokinetic data from the labeling for generic versions of Skelaxin®, but neither have submitted scientific data in support of their positions.

10. Based on my review of the data and underlying studies that are described in the current Skelaxin® labeling and in the pending Skelaxin® labeling supplement, I have been asked to assess the study results concerning the effects of food, age, and gender on the bioavailability of Skelaxin®. In addition, I have been asked to comment on whether the studies were adequately and appropriately designed and conducted. I have also been asked to assess whether the omission of the results of these clinical studies from the labeling for generic metaxalone products can pose safety and efficacy issues.

11. The data from King's clinical studies demonstrate that bioavailability of Skelaxin® varies as follows: an increase in bioavailability under fed conditions as compared to fasted conditions; an age-related increase in bioavailability in the fasted state only; and an increase in bioavailability when administered to females as compared to males. These results, in particular

the increase in bioavailability under fed conditions, indicate that safety and efficacy issues of clinical significance may exist. In the absence of any contrary clinical data, any presumption that the pharmacokinetic information can be omitted from the labeling for generic metaxalone products without affecting the safety and efficacy of those products is based in conjecture rather than scientific fact. It is my opinion that information describing the effects of food, age, and gender on the bioavailability of metaxalone is properly included in labeling -- both brand and generic -- and that omission of such information would pose safety and efficacy concerns.

12. I have also been asked to comment on the submissions made by Core and Mutual. In particular, I will explain why any variability in the individual pharmacokinetic data due to gastric phenomena does not negate the existence of a food effect. I will also explain the defects in any argument that the pharmacokinetic data lack clinical relevance because the studies only measured metaxalone blood levels and measured no clinical end points. I will also address criticisms regarding the utilization of single dose studies to demonstrate food effects; the utilization of a standardized high fat meal to demonstrate food effects; the utilization of a meta-analysis to determine age and gender effects; and the subject size of the clinical studies.

13. In my opinion, there is no evidence to support the conclusions drawn by Core and its expert or by Mutual that the bioavailability studies have no clinical relevance. I am not aware of any clinical data that contradict the pharmacokinetic data generated from the bioavailability clinical studies designed to demonstrate the effects of food, age, and gender on the bioavailability of Skelaxin®, or any clinical data that would cast doubt on their reliability. Not only are Core and Mutual's arguments unsupported by any clinical data, but they are also simply irrelevant to the question of whether the omission of results of bioavailability studies from the labeling for generic metaxalone products raises safety and efficacy concerns.

III. THE BIOAVAILABILITY OF SKELAXIN INCREASES SIGNIFICANTLY IN THE FED STATE AS COMPARED TO THE FASTED STATE

A. Clinical Studies Designed to Examine the Effect of Food on the Bioavailability of Skelaxin Demonstrate The Existence of a Significant Food Effect

14. I have reviewed Clinical Study AN151607-101 ("Study 101") entitled "Bioavailability Study of Skelaxin® (Metaxalone) 400mg Administered With and Without Food to Healthy Volunteers," which was designed as a single-dose, two period, randomized, crossover trial completed with 42 healthy volunteers.

15. Study subjects received two different treatments. For treatment A the volunteers were administered 1 x 400mg of Skelaxin® with food; for treatment B the volunteers were administered 1 x 400mg of Skelaxin® without food.

16. The primary objective of Study 101 was to evaluate the effect of food on the bioavailability of a 400mg tablet of Skelaxin® in healthy volunteers.

17. The results reported for Study 101 demonstrate that the bioavailability of a Skelaxin® 400mg tablet was increased when administered with food.

18. I have also reviewed Clinical Study AN151607-103 ("Study 103") entitled "Bioequivalence and Safety Study of Skelaxin® (Metaxalone) 1 x 800mg Tablet and 2 x 400mg Tablets Under Fasted and Fed Conditions in Healthy Volunteers," which was designed as a single-dose, four period, randomized, crossover trial completed with 59 healthy volunteers.

19. The volunteers of Study 103 received four different treatments. Treatment A involved administration of 1 x 800mg of Skelaxin® without food; Treatment B, administration of 2 x

400mg of Skelaxin® without food; Treatment C, administration of 1 x 800mg of Skelaxin® with food; and Treatment D, administration of 2 x 400mg of Skelaxin® with food.

20. Study 103 involved two objectives: (1) the determination of whether a 800mg tablet was bioequivalent to the 400mg tablet; and (2) the determination of whether food affected the bioavailability of Skelaxin®.

21. With respect to the first objective, Study 103 established that the administration of 1 x 800 mg Skelaxin® (metaxalone) tablet was bioequivalent to the administration of 2 x 400 mg Skelaxin® tablets.

22. With respect to the second objective, Study 103 established that the administration of Skelaxin® 1 x 800 mg tablet with food increased the rate and extent of absorption when compared to the administration of Skelaxin® 1 x 800mg without food.

23. Also with respect to the second objective, Study 103 established that the administration of Skelaxin® 2 x 400 mg tablets with food increased the rate and extent of absorption when compared to the administration of Skelaxin® 2 x 400mg tablets without food.

24. Study 101 was the initial study conducted to determine the effect of food on the bioavailability of Skelaxin®. As noted above, the results of Study 101 revealed that the administration of Skelaxin® with food dramatically increases its bioavailability as compared to its administration without food. The results of Study 101 were confirmed by the results of Study 103 and, based on the results of these two clinical studies, it is clear that the administration of Skelaxin® with food results in a significant increase in oral bioavailability.

B. Variability In the Individual Pharmacokinetic Data Does Not Negate the Existence of a Significant Food Effect

25. The submissions on behalf of Core and Mutual present no clinical data that refute the existence of the observed food effect. Core and its expert note that, in a few study subjects, fasted-state administration of metaxalone produced plasma concentration levels that exceeded those in the fed state. They speculate that this occurred due to fasted-state administration at a time that coincides with enhanced digestive functions that occur during Phase III of the migrating motor complex, or MMC. Even if true, this theory does not support Core's position.

26. The results of King's studies clearly establish the existence of a significant food-effect. Notably, the study analyses include the individual subject data discussed by Core's expert. In the absence of clinical data refuting the results of the studies, the statements made by Core and its expert have no basis. Moreover, the bioavailability of all drugs, including drugs that have food effects such as metaxalone, would be affected by this allegedly normal enhanced digestive process. Accordingly, its occurrence in the King studies provides no basis to reject or even question King's food effect data. The purported existence of a digestive function that could increase oral bioavailability of metaxalone in the fasted state does not and cannot negate the existence of a significant, clinically established food effect. Finally, assuming *arguendo* that this gastric phenomena exists, knowledge that Phase III of the MMC occurs when fasting and that administration of metaxalone (or any other drug) during this phase may enhance bioavailability cannot be used by practitioners to determine proper dosage and administration because it is impossible to predict exactly when the enhanced digestive process will occur, so there is no way for patients or their physicians to ensure that drug products are taken at a time that coincides with Phase III of the MMC.

V. THE BIOAVAILABILITY OF SKELAXIN IS AFFECTED BY AGE AND GENDER

A. Clinical Studies Designed to Examine the Effect of Age and Gender on the Bioavailability of Skelaxin and the Meta-Analysis

27. I have reviewed Clinical Study ELN 151607-105 ("Study 105") entitled "A Study to Evaluate the Pharmacokinetics of Skelaxin® (Metaxalone) 2 x 400mg Tablet Administered to Young and Elderly Volunteers Under Fed and Fasted Conditions," which was designed as a single-dose, randomized, two-period crossover trial and completed with 44 volunteers.

28. I have also reviewed Clinical Study AN151607-106 ("Study 106") entitled "A Study to Evaluate the Effect of Gender on the Pharmacokinetics of Skelaxin® (Metaxalone) 2 x 400mg Administered to Healthy Volunteers" which was designed as a single-dose, parallel design trial and completed with 48 volunteers. The study was designed to determine the effect of gender on the pharmacokinetics of 2 x 400mg tablets of Skelaxin® administered under fasted conditions to 24 male and 24 female volunteers.

29. I have also reviewed the meta-analysis of Study 105 and Study 106 conducted in combination with Study 101 and Study 103 to investigate the effect of age and gender on the bioavailability of Skelaxin® in both the fed and fasted states. The results of Study 105, Study 106, and the meta-analysis revealed that, in the fed state, age has little or no effect upon the bioavailability of Skelaxin® -- regardless of gender. In contrast, in the fasted state, bioavailability was statistically increased with an increase in age -- also regardless of gender. Moreover, in both the fed and fasted states, bioavailability of Skelaxin® is higher in females than in males.

B. The Age-Effect Data Is Statistically Significant

30. Based on the results of the clinical studies and the meta-analysis, it is clear that administration of Skelaxin® with food can cause a statistically significant increase in its oral bioavailability. In addition, Study 105, Study 106, and the meta-analysis reveal that in the fasted state, bioavailability was statistically increased with an increase in age. Moreover, it is clear that the age-related variations in the bioavailability of metaxalone are minimized when Skelaxin® is administered in the presence of food.

31. The data indicate that age is much more strongly associated with bioavailability in the fasted condition than in the fed condition, and Core and its expert fail to refute this fact. Based on the studies and the meta-analysis, it is clear that the estimated effect of age on AUC under fasted conditions is approximately three to four times larger than the estimated effect under fed conditions. The difference between the estimated effect of age on C_{max} under fasted vs. fed conditions is even larger.

VI. THE LACK OF EVIDENCE REGARDING CLINICAL RELEVANCE DOES NOT CONSTITUTE EVIDENCE OF CLINICAL IRRELEVANCE

32. It is my understanding that Study 101 and Study 103 were submitted to the FDA and that those studies are currently described in the Clinical Pharmacology section of the labeling for Skelaxin®. I have reviewed the current labeling for Skelaxin®. Specifically, the labeling describes the results of Study 101 and Study 103 that administration of Skelaxin® with food results in a significant increase in oral bioavailability of metaxalone.

33. I have also reviewed the pending supplement proposing revised labeling for Skelaxin® incorporating the data gathered from Study 105, Study 106, and the meta-analysis. The proposed labeling includes the pharmacokinetic data that demonstrate the effects of age and gender on oral bioavailability and the effect of food upon the variations in bioavailability caused by differences

in age. Based on these statistically significant data, the proposed labeling also includes a recommendation that Skelaxin® be administered with food to ensure more predictable plasma levels of metaxalone.

A. Scientific Data Cannot Be Omitted from Labeling In the Absence of Clinical Evidence Demonstrating that Such Omission Does Not Have an Impact on Safety or Efficacy

34. The results of King's bioavailability studies should not be omitted from the labeling for generic metaxalone products. Based on my experience at and with FDA, this is the first time I have seen the Agency consider deletion of this type of scientific data from a generic label. I believe that the pharmacokinetic data is important for physicians who must make decisions concerning the optimal dosage and administration of Skelaxin® and all other drug products, whether innovator or generic. Because the results of bioavailability studies provide information that can be relevant under specific conditions and to specific patients in determining the optimal dosage regimen, it is critical that this information be provided in both brand and generic labels. I believe that it is of the utmost importance that such scientific data not be deleted from the label of any drug.

35. Core and Mutual fail to identify any clinical evidence indicating that the bioavailability data are clinically irrelevant and, instead, base their arguments on supposition. Each argues that because it is unknown whether or not there is a correlation between changes in plasma concentration levels and safety or efficacy, the pharmacokinetic data are clinically irrelevant. However, Core and Mutual err in presuming that the lack of evidence showing a correlation between plasma levels and safety or efficacy means that this information is not important. Changes in bioavailability are not immaterial to safety and efficacy. Any omission of pharmacokinetic data from a product's labeling could raise serious concerns regarding safety and

efficacy, and should not be undertaken without considerable scientific discussion and debate. To do so would open a Pandora's box where all kinds of data can be deleted, subject only to a particular reviewer's personal bias.

36. It is undisputed that, despite having a long history of use, information concerning metaxalone remains incomplete. For instance, Skelaxin®'s mode of action and drug-drug interactions currently remain unknown. In fact, until recently, no one had studied the pharmacokinetics of Skelaxin®. However, recent studies have demonstrated that metaxalone pharmacokinetics are affected by food. For FDA to require fed/fasting studies and not to include the information in the labeling -- on the basis that it is irrelevant -- would be a violation of the Helsinki Resolutions, whereby unnecessary clinical research in humans is precluded.

B. It Is Irrelevant That the Clinical Studies Did Not Measure Clinical Endpoints, and Instead Measured only Blood Plasma Levels of Metaxalone

37. Core and Mutual also err in assuming that because the King studies were not designed to measure clinical endpoints, the pharmacokinetic data are clinically irrelevant. Studies investigating, directly, the clinical effect of a food effect are rare. Instead, bioavailability studies and bioequivalence studies, such as Studies 101 and 103, that do not measure clinical endpoints, are routinely conducted and data generated from such studies are included in product labeling. Core and Mutual do not dispute that the FDA requires submission of *in vivo* bioequivalence studies in both the fed and fasted states because of the existence of a food effect. FDA requires these studies to eliminate the concerns that stem from the potential for different safety and/or efficacy profiles. As such, the safety and efficacy of generic versions of Skelaxin® can only be demonstrated by bioequivalence studies which themselves do not measure clinical endpoints. In fact, if FDA were to agree to omit the pharmacokinetic data from labeling for generic

metaxalone products, the Agency would be essentially reversing its determination that generics must show bioequivalence under both fed and fasted conditions. Based on my experience at and with FDA, it is my opinion that if the information is omitted and fed bioequivalence studies were still to be required, such clinical studies would be technically unnecessary and therefore possibly unethical.

38. Accordingly, although no clinical endpoints were measured, based on the results of clinical studies, including Studies 101 and 103, FDA has acknowledged the import of the food effect data. In my opinion, the omission of the pharmacokinetic data demonstrating the existence of food, age, and gender effects from the labeling for generic products that require *in vivo* bioequivalence testing, such as metaxalone, is scientifically inappropriate.

39. The fact that King's studies were not designed to measure clinical endpoints does not negate the results of those studies demonstrating that food, age and gender each have a significant effect on the bioavailability of metaxalone. In addition, the failure to measure clinical endpoints is not evidence that there is no correlation between plasma levels of metaxalone and safety or efficacy. Thus, the fact that the clinical studies did not measure clinical endpoints is simply irrelevant to the question of whether the pharmacokinetic data can be omitted from the labeling without raising issues of safety and efficacy.

40. Likewise, it cannot be presumed that because the King's studies only measured blood plasma levels of metaxalone, that the resulting pharmacokinetic data are clinically irrelevant. At the very least, blood levels have clinical relevance to the extent that a drug such as metaxalone must reach the blood in order to have clinical effect. Changes in blood level can be an indication that there will be changes in pharmacologic effect. In fact, the bioavailability of an orally

administered drug product with a systemic clinical effect is critical to such effect. Certainly, I am not aware of any scientific data that support an assertion that blood levels of metaxalone do not assure a clinical effect. Thus, in the absence of clinical evidence that there is no nexus between the blood levels of Skelaxin® and its clinical safety or efficacy, there is no scientific basis for assuming that the pharmacokinetic data are immaterial to determining safe and effective use of Skelaxin®.

VII. THE CLINICAL STUDIES WERE PROPERLY DESIGNED AND CONDUCTED

41. Based on my experience at FDA and as a pharmacokineticist, it is my opinion that, contrary to Core and Mutual's criticisms, King's clinical studies -- Studies 101, 103, 105 and 106 -- were designed and conducted in a scientifically appropriate manner, fully consistent with FDA's Guidance for Industry, *Food-Effect Bioavailability and Fed Bioequivalence Studies*, FDA, CDER (Dec. 2002), and the Agency's predecessor draft guidance. The pharmaceutical industry commonly conducts food-effect studies in accordance with this guidance and data generated by single-dose studies investigating the effects of a standardized high fat meal are commonly described in prescription drug product labeling. Likewise, FDA and the pharmaceutical industry have endorsed the use of meta-analyses for pooling and analyzing data from two or more studies. As such, adherence to FDA's guidance provides no basis to criticize the studies or their results.

A. The Use of a Standardized High-Fat Meal To Determine the Existence of a Food Effect Is Appropriate

42. Core and Mutual theorize that different studies investigating the effects of meals other than the standardized high fat meal would reveal that co-administration of metaxalone with food of different compositions has varying effects on the bioavailability of metaxalone. From this,

Core and Mutual conclude that the pharmacokinetic information may properly be omitted from the labeling for generic metaxalone. This conclusion, however, is flawed. In the absence of clinical data, it is impossible to conclude that the fed-state bioavailability of metaxalone would be affected differently by the administration of meals other than the standardized high-fat meal used in the clinical studies. Contrary to the assertions made by Core and Mutual, the use of the standardized high fat meal does not undermine the results of the clinical studies designed to assess the effect of food on the bioavailability of metaxalone in any way.

43. In fact, the FDA guidelines recommend that food-effect bioavailability studies and fed bioequivalence studies be conducted using the standardized high-fat meal. Core and Mutual do not dispute that the fed bioequivalency requirement that for generic metaxalone is satisfied only by conducting clinical studies that utilize the standardized high fat meal. Indeed, if the caloric breakdown of the meal significantly differs from the prescribed standardized high-fat meal, a scientific rationale for the difference is required.

44. Moreover, although the FDA allows New Drug Applicants to conduct food-effect bioavailability studies using meals that differ from the standardized high fat meal for exploratory or label purposes, the FDA requires that one of the meals investigated be the standardized high-fat meal. FDA has recognized that food-effect studies utilizing the standardized high-fat meal provide important pharmacokinetic data that should be incorporated into labeling. As discussed above, based on Studies 101 and 103, FDA required the conduct of fed studies utilizing the standardized high fat meal, and included the pharmacokinetic data that resulted from the studies in the Skelaxin® labeling.

45. Thus, in my opinion, any suggestion that the utilization of the high-fat meal renders the clinical studies useless and of no practical or clinical import is contrary to FDA policy and unjustified. In particular, it is my opinion that this alleged defect in the clinical study protocol is certainly no basis for asserting that the omission of the pharmacokinetic data from the clinical studies would be proper.

46. The fallacy of the criticism is further compounded by the lack of any actual clinical data suggesting that the fed-state bioavailability of metaxalone would differ when administered with a meal other than the standardized high-fat meal. Co-administration with different meals may *or may not* impact bioavailability differently than co-administration with the standard high fat meal. The bioavailability of different drugs is impacted differently by co-administration with various types of meals (as the exhibits to the Core and Mutual submissions indicate), and absent data from studies conducted on metaxalone, it is impossible to predict how, if at all, the bioavailability of metaxalone would differ when co-administered with various types of meals.

47. Core and Mutual also err in assuming that the *possibility* that bioavailability may be impacted differently when metaxalone is co-administered with different types of meals means that information on known food-effects should be omitted from generic metaxalone labeling. Contrary to Core and Mutual's suggestion, as discussed above, FDA has never required that all possible food effects be clinically investigated before information about known food effects is incorporated into product labeling.

B. The Use of a Single Dose Study To Determine the Existence of a Food Effect Is Appropriate

48. Core and its expert, Dr. Bass, also criticize King's use of single-dose studies, arguing that at steady-state, the observed food effects would be non-existent or minimal. This criticism is

also scientifically unsupported and unjustified. FDA's food effect guidance recommends use of a single-dose design. The pharmaceutical industry routinely conducts food-effect studies in accordance with this guidance and data generated from single-dose studies are commonly described in prescription drug product labeling. Moreover, bioequivalence studies submitted by generic drug companies (including those seeking to market generic versions of Skelaxin®) are also required by FDA to be single dose studies. The criticism of the use of a single dose study for assessing food-effects is contrary to FDA rationale for requiring the single dose study.

C. The Clinical Studies Are Properly Sized and The Use of a Meta-Analysis To Investigate the Effects of Age and Gender Is Appropriate

49. Core and Mutual criticize the number of subjects included in each of the clinical studies designed to assess the effects of food, age, and gender on the bioavailability of Skelaxin®. Based on my review, the studies were appropriately sized, given their purpose. Moreover, in my experience, studies conducted to investigate the impact of food, age, or gender on bioavailability typically include 16-45 patients, which is fully consistent with Studies 101, 103, 105 and 106. I note that bioavailability studies submitted by generic drug companies, such as Core and Mutual, in support of their ANDAs typically do not include a greater number of subjects than did the King studies, and indeed often include fewer subjects. In sum, Core and Mutual's criticism is baseless. The studies were sized appropriately.

50. In connection with their criticism of the number of subjects in the clinical studies, Core and Mutual also criticize the utilization of a meta-analysis to assess the age and gender effects. Based on my experience at FDA and as a pharmacokineticist, a meta-analysis is commonly used and is an appropriate tool to evaluate the data from two or more clinical studies bearing on the

same question. In addition, meta-analyses provide powerful measures of effects that might otherwise go unnoticed.

51. Contrary to the criticisms asserted by Core and Mutual, it is my opinion that it was entirely appropriate to pool the data from Studies 101, 103, 105 and 106 to determine the effects of age and gender on the bioavailability of Skelaxin® in the fed and fasted states. Indeed, King's use of the meta-analysis obviates Core and Mutual's stated concern about the size of King's studies.

CONCLUSION

52. In sum, the results of King's studies designed to assess the effects of food, age, and gender should not be omitted from the labeling for generic versions of Skelaxin.® Based on my experience at FDA and as a pharmacokineticist, it is my opinion that such pharmacokinetic data should not be omitted from labeling, particularly in the absence of any clinical data that show that changes in bioavailability are immaterial to safety and efficacy. It is also my opinion that the arguments Core and Mutual have presented in support of their position that the pharmacokinetic data can be removed from the labeling for generic metaxalone products are without support and without merit.

I declare under the penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

7-21-04

Date

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CURRICULUM VITAE

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EDUCATION:

Wayne State University Detroit, Michigan	B.S. Chemistry	1964
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	Ph.D. Chemistry	1966-69
University of California College of Pharmacy Medical Center San Francisco, Ca.	Biopharmaceutics	1974-75
Carnegie-Mellon University Pittsburgh, Penn.	Senior Executive Training	1985
Senior Executive Institute United States Government Charlottesville, Virginia	Senior Executive Training	1986

PRESENT POSITIONS

President-Elect American Association of PharmaceuticalScientists	10/03-Present
Pharmaceutical Consultant Jerome Philip Skelly, Ph.D., Ltd.	1/93-Present
Chairman of the Board of Directors	3/02-10/03
Founding Officer & Member, Board of Directors Pharmaceutical Quality Research Institute	6/99-10-03
Past-Commodore Mount Vernon Yacht Club Alexandria, Virginia	11/98-Present
Professor of Biopharmaceutics (Adjunct) Division of Biopharmaceutics College of Pharmacy University of Cincinnati	5/93-Present
Associate - Westfield Partners, LLC Wilton, Conneticut	1/03-Present
Strategic Advisory Board Velquest Cororation Hopkinton, Massacheusetts	6/00-Present
Projects Consultancy Board I.D.E. Group Istanbul, Turkey	5/99-Present

PREVIOUS EXPERIENCE:	*Commodore* *CEO & Chairman of Board of Directors* *Mount Vernon Yacht Club* *Alexandria, Virginia*	*11/98-11/2000*
	Executive Vice President *Scientific and Regulatory Affairs* *Copley Pharmaceutical Inc.* *Boston, Massachusetts*	*1994-1997*
	Scientific Advisory Board *American Pharmaceutical International* *Cincinnati, Ohio*	*1995-2002*
	Advisory Board of Directors *Biovail Research Corporation* *Toronto, Canada*	*2/93-1/95*
	Senior Executive Service *Government of the United States* *Washington, D.C.*	*5\86-1\93*
	Deputy Director *Office of Research Resources* *Center for Drug Evaluation and Research, FDA*	*5/88-1/93*
	and *Associate Director for Science* *Office of Generic Drugs* *Center for Drug Evaluation and Research, FDA*	*10/90-6/92*
	Acting Director *Office of Research Resources* *Center for Drug Evaluation and Research* *Food and Drug Administration*	*5/88-4/91*
*	*Chairman* *CDER Combined Federal Campaign* *Food and Drug Administration*	*1989*
	Director *Division of Biopharmaceutics* *Center for Drug Evaluation and Research* *Food and Drug Administration*	*1/83-5/88*
	Program Manager *Biopharmaceutics Research and Review Program* *Center for Drugs and Biologics* *Food and Drug Administration*	*8/83-1/93*
	Deputy Director *Division of Biopharmaceutics* *Center for Drugs and Biologics* *Food and Drug Administration*	*11/79-1/83*

* This was the first and only CDER campaign ever (i.e., over a 20 year period through 1992) to attain or surpass its goal.

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Chief, Pharmacokinetics and
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University of California, School of Pharmacy
University of California Medical Center
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Chief, Clinical Research Branch, and
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Bureau of Drugs/FDA *1972-1975*

Chemist, Division of Metabolic and
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Research and Teaching Assistant
Wayne State University
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Michigan Abrasive Company
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MEMBER OF EDITORIAl BOARDS:

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AWARDS/COMMENDATIONS:

Good Conduct Medal — *1958*
U.S. Army

Letter of Commendation, (Professional Citation) — *1958*
U.S. Army

Letter of Commendation — *1963*
Michigan Abrasive Co.

Elected to Phi Lambda Upsilon
(Chemistry Honors Society) — *1967*

Quality Performance Raises — *1973 & 1979*
Outstanding Performance Evaluations (Civil Service): — *1982,1983,1985 & 1987*
Outstanding Performance Evaluations (Senior Executive Service): — *1990*
Senior Executive Service Bonus — *1990*

Letter of Commendation:
Research and Facility Planning
Executive Director for Regional Operations
Food & Drug Administration — *1979*

Award of Merit, (FDA's Highest Award)
"For Exceptional Achievement in Repeatedly Providing Expert Scientific Support Leading to Successful Litigation Against Firms Marketing Unapproved Drug Products"
Food and Drug Administration — *1981*

Public health Service - Equal Opportunity Achievement Award
"For Outstanding Leadership in Recruitment & Training of Personnel & Outstanding Achievement in Fostering Equal Employment Opportunity in the Public Health Service" — *1986*

Public health Service - Equal Opportunity Achievement Award
"For Providing Equal Consideration of Highly Qualified Staff Fellows by Resolving Extremely Difficult Personnel Issues which Fostered Unequal Remuneration and Hindered Promotion". — *1988*

Commissioners Special Citation
"As a Member of the 'CANDA Guidance Manual Taskforce', Creating Effecient & Effective Application Development for the Benefit of FDA, Industry and the Public".
Food and Drug Administration — *1993*

Certificate of Appreciation
National Drug Manufacturing Drug Quality Control
Food and Drug Administration — *1996*

Recognition Award
"For His Leadership in the Globalization of Quality Standards for the Pharmaceutical Sciences and His Devoted Service to the Advancement of Pharmaceutical Science".
American Association Indian Pharmaceutical Scientists — *1996*

Distinquished Service Award
"In recognition of His Scholarly Effort in Advancing AAPS and the Pharmaceutical Sciences.
American Association of Pharmaceutical Scientists
Toronto, Canada — *Nov., 2002*

GOVERNMENT CLEARANCE

Full Field Investigation: Eligible to Occupy Critical Sensitive Position	1/79
200-C Medical Inspection Credentials	1/79

MILITARY SERVICE:

United States Army, Volunteer	10/56 to 10/58
Letter of Commendation	10/58
Good Conduct Medal	10/58
Honorable Discharge	1962

PROFESSIONAL SOCIETY MEMBERSHIPS:

FELLOW:

American Association of Pharmaceutical Scientists
American College of Clinical Pharmacology
Americxan Association of Indian Pharmaceutical Scientists

LIFE MEMBER:

Phi Lambda Upsilon (Chemistry Honors Society)

SUSTAINING MEMBER AND CHARTER MEMBER:

American Association of Pharmaceutical Scientists

FDA CHARTER MEMBER:

Research Society of America - Sigma Xi
FDA Alumni Association

OTHER MEMBERSHIPS:

Ameciacn College of Clinical Pharmacology
American Chemical Society

KEY COMMITTEES:

Academic and National Center/Institute:

Chairman of Board Of Directors	2002-2003
Member of the Board of Directors Pharmaceutical Product Quality Research Institute Arlington, Virginia	6/99-2003
Center - Compendial Policy Facilitation Group Center for Drug Evaluation & Research, Food and Drug Administration	1990-1993

Sponsoring Officer, Professor Gordon Amidon
University of Michigan, Sabbatical @ FDA
CDER, FDA — *1990-1991*

USP 1990 Quinquennial Convention
FDA Representative
Washington, D. C. — *1990*

International Industrial Pharmacy Conference
University of Texas, School of Pharmacy
Conference Committee (Annual)
Austin, Texas — *1977-1993*

Advisory Committee
Carnegie Mellon University
Senior Executive Seminar
Pittsburgh, Pennsylvania — *1985-1992*

Consultant on Controlled Release Drugs
Division of Drugs
National Institute of Hygenic Science
Japanese Ministry of Health and Welfare
Osaka & Tokyo, Japan — *1987-1990*

Promotion Review Committee
Full Professor Solomon Stavchanski
School of Pharmacy
University of Texas
Austin, Texas — *1987*

Research Scientist Promotion Panels
National Institute of Drug Abuse
Rockville, maryland — *1983-1985*

Research Scientist Promotion Panels
Exec. Dir. Reg. Oper. Research Centers
Rockville, maryland — *1980-1982*

Research Scientist Promotion Panels
National Center for Toxicological Research
Pine Bluff, Arkansas — *1979-1981*

Promotion (Tenured) Review Committee
Assoc. Prof. Betty Ann Hoerner
School of Pharmacy
University of California
San Francisco, California — *1980*

Wayne State University
Alumni Assoc. Committee
Washington D.C. Chapter — *1969-1978*

International:

AAPS Globalization Committee — *2003-Present*

FDA Alumni Association - International Committee — *2002-Present*

Committee Member
BioInternational '94
FDA, HPB, EC Regulatory Bodies, FIP, & AAPS
Munich, Germany — *1993-1994*

Committee Member
BioInternational '92
Food and Drug Administration,
Canadian Health Protection Branch,
European Commission Regulatory Bodies
Federation Internationale Pharmaceutique, &
American Association of Pharmaceutical Scientists
Bad Homberg/Frankfort, Germany — *1991-1992*

European Community Ad Hoc Committee
Satellite Meeting
On the Definition of Bioavailability
Federation International Pharmaceutique
Munich, Germany — *1989*

Health Protection Branch Laboratories
Site Visit Committee,
Department of Health and Welfare
Ottawa, Canada — *1989*

Committee Member
BioInternational '89
Canadian Health Protection Branch
Food and Drug Administration/American Association of
Pharmaceutical Scientists — *1988-89*

International Advisory Scientific Programme Committee
Third International Conference on Drug Absorption
Edinburgh, Scotland — *1988*

International Advisory Board
International Conference of Pharm. Services
and Clinical Pharmacology
Jerusalem, Israel — *1988*

Member International Pharmaceutical
Scientific Affairs Task Force
American Association of Pharmaceutical Scientists
Arlington, Virginia — *1988*

Collaboration, Laboratory and Consultant
Division of Drugs
National Institute of Hygenic Science
Ministry of Health and Welfare
Osaka and Tokyo, Japan — *1987-1991*

Corresponding Member
Working Group, Dissolution Testing
Federation Internationale Pharmaceutique
Saskatoon, Sask., Canada — *1986-1989*

Consultant, World Health Organization
NODCAR
National Organization on Drugs
Dokkai, Cairo, Egypt — *1986*

Professional:

Chairman: Fellows Election Committee - AAPS
Arlington, Virginia — *2003*

Governance Task Force - AAPS
Arlington, Virginia — *2003*

Fellows Task Force - AAPS
Arlington, Virginia — *2002-2003*

Chairman & Planning Committee Member
Workshop of "The Paperless Laboratory: 'Finaly a Reality'
AAPS & Parenteral Drug Association
Arlington, Virginia — *June, 2002*

Executive Committee
Regulatory Affairs Section - AAPS — *1993-2002*

Chairman Fellows Election Committee
American Association of Pharmaceutical Scientists — *1995-96*

Fellows Election Committee — *1993-94*
American Association of Pharmaceutical Scientists — *1996-2001*

Chairman, Fellows Nominating Committee — *1993-94*
Regulatory Section, AAPS — *1997-2001*

Outside Reviewer
Fellows Selection Committee - AAPS — *1997-1998*

Executive Council
Elected Member at Large - — *1/92-1/95*

Planning Committee Member and Session Chair
Bioavailability and Bioequivalence Symposium
Drug Information Association
Rockville, Maryland — *9/94*

Vice President for Science: Search Committee
American Association of Pharmaceutical Scientists — *1993*

Organizer and Committee Member
Scale-Up of Liquid & Semisolid Disperse Systems
AAPS-FDA Workshop
Arlington, Virginia — *1993*

Chairman and Committee Member
Scale-Up of Solid Oral Controlled Release Dosage Forms
AAPS-FDA Workshop
Arlington, Virginia — *9/92*

Chairman
Pharmacokinetics, Pharmacodynamics, & Drug Metabolism Section
American Association of Pharmaceutical Scientists
Alexandria, Virginia — *1/91-1/92*

Co-Chairman and Committee Member
Scale-Up of Solid Oral Immediate Release Dosage Forms
AAPS-FDA Workshop
Arlington, Virginia — *1991*

Chairman of Sponsoring Section and Committee Member
PPDM 'OPEN FORUM-I'
"Pharmacokinetics/Pharmacodynamics, Where is it Going?"
Pharmacokinetics, Pharmacodynamics, & Drug Metabolism Section
American Association of Pharmaceutical Scientists
Washington, D.C. — *1991*

Co-Chairman and Committee Member
Integration of Pharmacodynamics Pharmacokinetics & Toxicokinetics
in Rational Drug Development - Conference
AAPS/FDA/ASCPT - Arlington, Virginia — *1991*

Committee Member and Consensus Session Chairman
Analytical Methods Validation
Bioavailability, Bioequivalence and Pharmacokinetics
Studies-Conference AAPS/FDA/FIP/HPB/AOAC — *1990*

American Association of Pharmaceutical Science
Task Force on Batch Size and Bioavailability — *1990-1991*

Chairman Elect, & Member of Executive Committee - AAPS
Pharmacokinetics, Pharmacodynamics, Drug Metabolism Section — *1/90-12/90*

Fellows Selection Committee
American Association of Pharmaceutical Scientists
Alexandria, Virginia — *1990*

Session Chairman and Committee Advisor
Principles and Criteria for the Development &
Optimization of Topical Drug Products
FDA/AAPS - Arlington, Virginia — *1990*

Chairman: Fellows Nomination Committee
Pharmacokinetics, Pharmacodynamics and
Drug Metabolism Section, AAPS — *1990*

Use of Animals as Substitutes for Humans in Oral
Bioavailability and Bioequivalence Studies
Division of Biopharmaceutics, FDA and PMA — *1989*

Workshop Cosponsor and Planning Committee Member
In-vivo Percutaneous Penetration/Absorption
FDA/AAPS/ACSF — *1989*

Vice Chairman
Pharmacokinetics, Pharmacodynamics and
Drug Metabolism Section, AAPS — *1/89-12/89*

Facilitator
PMA Division of Biopharmaceutics Workshop
Pharmacokinetics of Metabolites
Bethesda, Maryland — *1989*

Workshop Chairman and Committee Member
Controlled Release/Modified Release
Dosage Forms, In-Vivo and In-Vitro Testing
FDA/AAPS/USP/FIP — *1988*

Executive Committee
Pharmacokinetics, Pharmacodynamics and Drug
Metabolism (PPDM) Section, AAPS — *9/87-12/92*

American Association of Pharmaceutical Scientists
1989 Annual Meeting Program Planning Committee — *9/88-10/89*

Chairman, Strategic Planning Committee:
Pharmacokinetics, Pharmacodynamics and
Drug Metabolism Section, AAPS — *9/88-1/90*

Co-Chairman, Program Committee
Pharmacokinetics, Pharmacodynamics & Drug Metabolism Section
AAPS National Meeting. Atlanta,Georgia — *9/88-10/89*

Facilitator
Division of Biopharmaceutics (FDA)- and
Drug Metabolism Section (PMA), Workshop
Role of Pharmacokinetics & Metabolites in
Development of Racemic Drugs
Bethesda, Maryland — *1988*

Ad Hoc Committee on Drugs in the Elderly
and Testing the Pharmacokinetics Screen
Am. Soc. Clin. Pharm. Therap.
Rockville, Md. — *1987-1989*

Committee on Regulatory and Government Affairs
Controlled Release Society — *1986-1988*

Co-Chairman and Co-Sponsor Symposium Planning Committee:
Pharmacokinetics of Antibiotic and Anti-cancer Agents
FDA/AAPS/ACCP, AAPS National Meeting
Boston, Massachusetts — *1987*

Workshop Planning Committee and Co-Sponsor:
Targeted Drug Delivery Systems
FDA/AAPS/ACCP
AAPS National Meeting
Boston, Massachusetts — *1987*

Workshop Planning Committee and Co-Sponsor:
Principles of Practices of In Vitro Percutaneous Studies:
Relevance to Bioavailability and Bioequivalence
AAPS 1st National Meeting in Washington, D.C.
FDA/AAPS/University of California — *1986*

Co-Chairman and Workshop Program Planning Committee:
Controlled Release Dosage Forms: "Issues and Controversies"
ASCPT/FDA/DIA and APS — *1985*

Planning Committee
Biopharmaceutics Considerations in IND and NDA Workshop
Drug Information Association — *1985*

Editorial Board
Clinical Research Practices and Drug Regulatory Affairs — *1985-1990*

Education Committee:
American College of Clinical Pharmacology — *1984-1985*

Admissions Committee:
Research Society of America
FDA Section — *1972-1973*

Food and Drug Administration:

CANDA Guidance Manual Task Force
CDER Member
Food and Drug Administration — *1992-1993*

Co-Chairman
CANDA-Biopharmaceutics
CDER-PMA Taskforce
Food & Drug Administration &
Pharmaceutical Manufacturers Assoc. — *1990 - 1992*

Pharmacokinetics Fellowship Committee
Center for Drug Evaluation and Research
Food and Drug Administration — *1990-1991*

Center for Drug Evaluation and Research
Equal Employment Opportunities Advisory Council
Food and Drug Administration — *1989-1990*

Staff College Executive Committee
Center for Drug Evaluation and Research
Food and Drug Administration — *1988-1991*

Co-Chair
Center for Drug Evaluation and Research
United States Pharmacopoea
Policy Facilitation Group
CDER-FDA — *1990-1993*

Compendial Liaison Committee
Center for Drug Evaluation and Research
Food and Drug Administration — *1990-1993*

Chairman
Combined Federal Campaign
Center for Drug Evaluation and Research
Food & Drug Administration — *1989*

CDER - Staff and Policy Committee
Center for Drug Evaluation and Research
Food & Drug Administration — *5/88-1992*

Research Evaluation Committee
Center for Drug Evaluation and Research
Food & Drug Administration — *1/89-11/90*

Research Steering Committee
Center for Drug Evaluation and Research
Food & Drug Administration — *5/88-12/88*

PMA/FDA Committee
For Improved Communications — *1985-1986*

Chairman
Pharmacokinetics Fellowship
Center for Drugs and Biologics
Food & Drug Administration — *1985-1990*

Retrospective Regulation Review
Bioavailability/Bioequivalence Regulations
Center for Drugs and Biologics
Food & Drug Administration — *1983-1984*

Drug Dissolution Committee
Division of Biopharmaceutics
Bureau of Drugs
Food & Drug Administration — *1982-1984*

Merit Pay Board
Office of Drugs
Bureau of Drugs
Food & Drug Administration — *1981-1982*

Compendial Liaison Staff
Bureau of Drugs
Food & Drug Administration — *1977-1980*

Information Systems Users Committee
Bureau of Drugs
Food & Drug Administration — *1975-1979*

Bioequivalence/Bioavailability
Regulation Development Task Force
Bureau of Drugs
Food & Drug Administration — *1975-1979*

Theophylline Task Force
Bureau of Drugs
Food 7 Drug Administration — *1976-1978*

Statistical Subcommittee,
Compendial Liaison Staff
Bureau of Drugs
Food & Drug Administration — *1977-1978*

Project Officer,
Bioavailability/Bioequivalence Monograph Task Force
Division of Biopharmaceutics
Bureau of Drugs
Food & Drug Administration — *1975-1976*

Project Control Officer
Digoxin Bioavailability
Bureau of Medicine
Food & Drug Administration — *1972-1974*

Chairman,
Bureau of Drugs Bioavailability Committee
Bureau of Medicine
Food & Drug Administration — *1973-1974*

Member:
Bioavailability Committee
Bureau of Medicine
Food & Drug Administration — *1972-1974*

PROJECT OFFICER/FDA CONTRACTS

Bioavailability Testing of Selected Marketed Drugs	*John Wagner, Ph.D. Distinguished Professor University of Michigan Ann Arbor, Michigan*
Digoxin Bioavailability	*John Wood, Ph.D. Professor Of Pharmacy VA Commonwealth Un. Richmond, Virginia*
Clinical Pharmacology and Therapeutics Symposium	*American Society for Clinical Pharmacology and Therapeutics. Medical Sch Tulane University New Orleans, Louisianna*
Workshop on Biochemical Approaches to Clinical Pharmacology	*University of California School of Pharmacy San Francisco, California*
Methodology Development and Bioavailability Testing	*Sidney Riegelman, Ph.D. Professor and Chairman Department of Pharmacy University of California San Francisco, California*
Bioequivalence Survey of Selected Drugs	*Marvin Meyer, Ph.D. Professor of Pharmacy and Asst Dean-School Pharmacy University of Tennessee Memphis, Tennessee*
Intramuscular Injection as a Drug Delivery System	*Cannon Laboratories Reading, Pennsylvania*
C^{13} Labeled Glucocorticoid Synthesis and Bioavailability	*Stanford Research Inst. Palo Alto, California*
Collaborative Agreement with a Pharmaceutical Research Facility	*Ralph Shangraw, Ph.D. Professor,& Larry Augsberger,Ph.D. Professor of Pharmacy University of Maryland Baltimore, Maryland*
Aminoacidureas Inherited Disorders of Metabolism	*Bureau of Foods and Bureau of Medicine, FDA*

JUDICIAL PROCEEDINGS
FOOD AND DRUG ADMINISTRATION

Scientific Consultant

United States District Court
District of New Jersey
United States of America
vs
Pharmadyne Laboratories
and
Bernard A. Bedrick

Marketing of Unapproved Drugs
Spring 1980

Scientific Consultant

**United States District Court*
District of New Jersey
***United States of America*
vs
Premo Pharmaceutical Laboratories, Inc.
and
Seymour N. Blackman
Summer 1980

Scientific Consultant

****United States of America*
vs
Professional Veterinary Laboratories
 # 3-78 Civ. 192
June 6, 1979

Scientific Consultant

Affidavit filed on the matter of:
Oral Proteolytic Enzymes
Withdrawal of New Drug Applications
May 28, 1980

* *Case eventually resolved in Supreme Court.*

** *Affidavit filed to the United States District Court For the District of Minnesota.*

*** *As Special Consultant to Bureau of Veterinary Medicine.*

PRESENTATIONS:

SUPAC: Impact & challenges Faced by Industry *AAiPS Dinner Meeting* *Morristown, N.J.*	*April, 2003*
Summary of Regulatory Issues Facing the Paperless Lab. *Co-Chair,Moderator,and Sponsor AAPS-PDA Workshop* *'The Paperless Laboratory':"Finaly a Reality"* *Arlington, Va.*	*June, 2002*
Streamlining Drug Development *"Bridgining the US - European - Asian Gap"* *Harrison Clinical Research* *Philadelphia, Pennsylvania*	*April, 2002*
Co-Moderator *"FDA Speaks - We Listen"* *American College of Clinical Pharmacology* *Annual Meetring Symposium* *Tysons Corner, Virginia*	*October, 2001*
Scale-Up & Post Approval Changes *International Institute of Research* *Alexandria, Virginia*	*6-22-2000*
In-Vivo/In-Vitro Correlations *Second Pharmaceutical Sciences Conference* *Assiut University: Assiut, Egypt*	*Mar.8, 2000*
Scale-Up & Post Approval Changes *Immediate Release & Modified Release Drug Products* *Second Pharmaceutical Sciences Conference* *Assiut University: Assiut, Egypt*	*Mar. 9, 2000*
SUPAC - A Short Course: *American Association of Pharmaceutical Sciences* *Annual Meeting* *New orleans, Louisianna*	*November, 1999*
Regulatory Issues & Update *Where are We Headed?* *Phoenix Clinical Program* *"Design for the New Millenium"* *San Francisco, California*	*Oct. 18, 1999*
Regulatroy Issues & Update *Where are We Headed?* *Newark New Jersey*	*Oct. 14, 1999*
Moderator: Individual Bioequivalence *Phoenix International Symposium* *Montreal, Quebec*	*June, 1999*
Scientific & Regulatory Support - SUPAC *Center for Professional Advancement* *New Brunswick, New Jersey*	*June, 1999*
Chair, Drug Delivery Session *Phoenix Laboratory 10th Annual Symposium* *Montreal, Canada*	*June, 1999*

Scale-Up & Post Approval Changes *Formulations Forum* *Orlando, Fla.*	*March 1999*
Switchability - Prescribability! *What Measure of Bioequivalence Is Required?* *International Symposium* *Honoring Professor, Doctor Wolfgang Ritschel* *Cincinnati, Ohio*	*11/13/98*
Bioequivalence and/or In Vitro Testing *in Lieu of Clinical Efficacy* *University of Cincinnati* *Cincinnati, Ohio*	*11/12/98*
Scale-Up and Post Approval Changes *Solid Oral and Semi-Solid Percutaneous Dosage Forms* *University of Cincinnati* *Cincinnati, Ohio*	*11/12/98*
Will The FDA Allow The Use of In-Vitro Dissolution as *a Surrogate of Clinical Efficiacy?* *38th Annual Eastern Pharmaceutical Technology Meeting* *Whippany, New Jersey*	*10/15/98*
Regulatory and Industrial Considerations, and *Analytical Requirements for SUPAC* *Institute for Applied Pharmaceutical Science* *East Brunswick, New Jersey*	*5/18/98*
Regulatory Documentation and Testing *Requirements for SUPAC* *Institute for Applied Pharmaceutical Science* *East Brunswick, New Jersey*	*5/18/98*
Regulatory Requirement for Approval of *Generic Percutaneous Dosage Forms* *Institute for Applied Pharmaceutical Science* *East Brunswick, New Jersey*	*5/19/98*
In-Vivo - In Vitro Correlations *College of Pharmacy* *University of Connecticut* *Storrs, Conneticut*	*9/97*
Drug Approval! *Future Aspects of FDA* *Quo Vadis Medicamentum* *Bobeheim, Germany*	*4/97*
FDA Requirements for Scale-Up, Site Transfer, and *Formulation ChangesImmediate Release and Controlled* *Release Dosage Forms* *University of Cincinnati* *Cincinnati, Ohio*	*11/96*
Dermatopharmaceutics and Changing Requirements for *Pharmacokinetic and Pharmocodynamic Studies for Testing* *Topical Semi-Solid Dosage Forms* *University of Cincinnati* *Cincinnati, Ohio*	*11/96*

The Crises facing Science: Award Lecture *American Association of Indian Pharmaceutical Scientists* *AAPS Annual Meeting* *Seattle, Washington*	*10/96*
Drug Bioavailability, Bioequivalence Dissolution: Biopharmaceutics *National Drug Manufacturing and Quality Control* *FDA Field Inspectors Training Course* *DHHS - FDA - Univ. of Cincinnati* *Newark, New Jersey*	*8/96*
Individual Bioequivalence - Is it necessary? *Generic Pharmaceutical Industry Assn - Science Committee* *Newark, New Jersey*	*8/96*
Practical Aspects of Setting Specifications! Is the Tail Wagging the Dog? *AAPS - Eastern Regional Meeting* *Newark, New Jersey*	*6/96*
Dissolution Testing of Polymorphic Forms Can In Vitro Studies Serve as a Substitute for Human Bioequivalnce Testing? *Philadelphia Pharmaceutical Forum - Jefferson House* *Norristown, New Jersey*	*12/95*
Individual Bioequivalence, and Highly Variable Drugs *University of Cincinnati* *Cincinnati, Ohio*	*10/95*
Issues at The Cutting Edge of Science *IBE vs Average Bioequivalence* *Cincinnati, Ohio*	*10/95*
The Scientific Basis of Regulation *The Impact of Academic Pharmacy on Research, Education, and Public Policy. "A Tribute fo Prof. Ralph Shangraw"* *University of Maryland* *Baltimore, Maryland*	*4/95*
New Initiatives In Bioequivalence Assessment: *Symposium on Current Challenges in Bioavailability* *NAPM Annual Meeting, Puerto Rico*	*2/95*
Co-Chair and Panalist *Symposium on Proteins and Peptides* *AAPS & ACCP, Symposium and Frontiers Series*	*2/95*
Bioavailability/Interchangeability: Regulatory Viewpoint *Regulatory Viewpoint* *16 Annual Eino Nelson Memorial Conference* *Turnberry Isle Resort. Aventura, Florida*	*1/95*
Chair *Evolution of Biotechnology Regulations* *AAPS Annual Meeting* *San Diego, California*	*11/94*

Co-Chair and Symposium Rapporteur *9/94*
Bioavilability - Bioequivalence
Drug Information Symposium
Rockville, Maryland

World Wide Problems *9/94*
7th International Pharmaceutical Technology Symposium
Haccettepe University
Ankara, Turkey

Committee Member and Rapporteur, *6/94*
Bioequivalence: Quality Control and Therapeutic Surrogate
Munich, Germany

Potential Effects of Health Care Reform on the *5/94*
Pharmaceutical Industry
Fifth Annual Symposium
Phoenix International Life Sciences Symposium
Montreal, Canada

Rapporteur *5/94*
Bioequivalence Quality Control
and Therapeutic Surrogate
Bio International
Munich, Germany

Scale-Up and Site of Manufacturing Changes: *3/94*
Adequacy of In-Vitro Tests as a Surrogate for In-Vivo Testing
North Carolina Discussion Group
Research Triangle Park, North Carolina

Scale-Up of Solid Oral Dosage Forms *9/93*
Pharmaceutical Technology Conference
Atlantic City, New Jersey

Regulatory Assessment of Controlled Release Drugs *9/93*
Pharm Tech Conference
Atlantic City, New Jersey

In-Vitro/In-Vivo Correlations in Biopharmaceutics: *9/93*
"Scientific & Regulatory Considerations"
University of Cincinnati

Batch size Scale-Up of Solid Oral Dosage Forms *9/93*
University of Cincinnati
Cincinnati, Ohio

Changes Requiring Bioequivalence Testing: *6/93*
35th Annual International Industrial
Pharmaceutical Research Conference on Development of Oral Dosage
Forms for Poorly Bioavailable Drugs
University of Wisconsin
Lake Delton, Wisconsin

Evaluation of Regulatory Guideline Based on Case Histories 6/93
2nd International Conf. on Controlled Release Dosage Forms.
Zurich, Switzerland

In-Vitro/In-Vivo Correlations in Biopharmaceutics with Their
Scientific and Regulatory Implications
5th European Congress of Biopharmaceutics & Pharmacokinetics
Brussels, Belgium 4/93

How to Define a Panel of Volunteers
From Human Microsomes to Multinational Registration Files:
An Integrated Approach to Human Pharmacokinetics Development
Third Symposium
Brussels, Belgium 10/92

Regulatory Assessment of Controlled Drug Delivery
Pharmacy World Congress '92
Federation Internationale Pharmaceutique, Ipharmex, and
National Congress of French Pharmacists
Lyon, France 10/92

Round Table Discussion Leader
Bioequivalence Issues of Orally Administered,
Non-Systemically Available Drugs
AAPS 7th Annual Meeting
San Antonio, Texas 10/92

Medicines, Prolonged Release/Immediate Release
Is Treatment the Same?
Institute Pasteur de Lyon &
Centre de Droit de La Sante
Gerland, France 6/92

Plenary Session Moderator and Panalist
International Open Conference on
Dissolution, Bioavailability, and Bioequivalence
Canadian Health Protection Branch, USP and FDA
Toronto, Canada 6/92

Conference Committee - Bio International '92
Bioavailability - Bioequivalence &
Pharmacokinetics Studies Conference.
Panel Co-Chair and Panelist on
'Bioequivalence of Highly Variable Drugs II'
Bad Homberg/Frankfort, Germany 5/92

Case Histories:
First International Conference on
Oral Controlled Dosage Forms
Berlin, Germany 4/92

Scale-Up of Immediate Release, Solid Oral Dosage Forms
Pharmaceutical Development Subsection
PMA Annual Meeting; Washington, D.C. 4/92

Public Standards for Bioavailability and Bioequivalence
FDA Perspective
Thirty-First International Pharmacy Conference
Austin, Texas — *2/92*

Analytical Methods Validation for
Bioavailability and Bioequivalence Studies
Second Symposium on Drug Bioavailability
Santiago, Chile — *1991*

Evaluation of Controlled Release Dosage Forms
Regulatory Requirements - Controlled Release Symposium
Baltimore, Maryland — *1991*

Session Co-Chairman
Bioavailability and Bioequivalence and World Standards
Pharmacy World Congress - FIP
Washington, D. C. — *1991*

Shah, V. P. and Skelly, J. P.
Regulatory Requirements for Quality Control
and Assessment of Bioavailability and Bioequivalence
Pharmacy World Congress - FIP; Washington, D. C. — *1991*

FDA Guidelines for Topical and Transdermal System
Pharm. Tech. Conference: New York, N. Y. — *1991*

Analytical Methods Validation and Stability Studies
Australian Pharmaceutical Science Association
Adelaide, Australia — *1991*

Symposium Summation and Commentary
Australian Pharmaceutical Science Association
Adelaide, Australia — *1991*

The CDER Research Program
Therapeutic Goods Administration
Canberra, Australia — *1991*

U S Drug Approval Process: Sea Change or Temporary Turbulence
Therapeutic Goods Administration
Canberra, Australia — *1991*

Session Chairman and Panelist
Dermatological Therapeutic Products Workshop - II
Arlington, Virginia — *1991*

Regulatory Issues - Oral Controlled Drug Delivery
North Carolina Discussion Group
Raleigh, North Carolina — *1991*

Session Chairman and Committee Member
Workshop on Analytical Validation
AAPS-FDA. Arlington, Virginia — *1990*

Biopharmaceutics and Clinical Pharmacology of Non-Systemically Available G.I. Drugs: Regulatory Concerns, AAPS 5th Annual Meeting
Las Vegas, Nevada 1990

Reference Preparations for Bioavailability Studies Drug Registration in Europe: Update and Trends for the Future.
Brussels, Belgium 10/90

Sample Preparations for Several Drugs in Serum and Dissolution Media Prior to Liquid Chromatographic Analysis
Su, S. Y., Shiu, G. K., and Skelly, J. P.
FAESS Meeting
Cleveland, Ohio 10/90

A Model for Predicting Drug Isomer Plasma Levels from Oral Controlled Release Dosage forms: Application to (+) and (-) Propranolol
Rose, S., Leesman, G., Shah, V., Skelly, J. P., Amidon, G.
Controlled Release Society National Meeting
Reno, Nevada 6/90

Regulatory Considerations for Scale-Up of Controlled Release Products: Shah, V. P., and Skelly, J. P.
Controlled Release Society National Meeting
Reno, Nevada 6/90

Effect of In Vitro Specifications on In Vivo Product Performance
AAPS Eastern Regional Meeting
New Brunswick, New Jersey 6/90

Regulatory Issues of Controlled Release Products
Baweja, R., and Skelly, J. P.
AAPS Midwest Regional Meeting
Chicago, Illinois 5/90

AAPS/FDA/SPS Workshop: Principles and Criteria Development and Optimization of Topical Products
Arlington, Virginia 3/90

In Vitro Dissolution Testing:
Food and Drug Administration
Seattle, Washington 2/90

Oral Controlled Release Drug: Regulatory View
Baweja, R., and Skelly, J. P.
Professional Seminar Institute
Woodcliff Lake, New Jersey 4/89

Report Controlled Release Dosage Forms Workshop "Issues and Controversies".
Controlled Release/Modified Release Dosage Forms In Vivo and In Vitro Testing - Workshop
Washington, D. C. 12/88

Regulatory Concerns in Controlled
Release Drug Product Approval
National Institute of Hygenic Sciences
Tokyo, Japan — *11/88*

National Institute of Hygienic Science Seminar
Evaluation of Dosage Form Design -
Controlled Release Drug Products
Osaka, Japan — *11/88*

Use of Animals in Lieu of Humans In Bioequivalence Studies
Universidad De Chile
International Symposium on Drug Bioavailability
Santiago, Chile — *10/88*

Development of In Vitro Methods for the
Evaluation of Controlled Release Dosage Forms
Universidad De Chile
International Symposium on Drug Bioavailability
Santiago, Chile — *10/88*

Bioavailability and Bioequivalance
FDA Perspective
Universidad De Chile
International Symposium on Drug Bioavailability
Santiago, Chile — *10/88*

Topical Drug Delivery - Regulatory Issues
Applied Pharmaceutical Science Center
East Brunswick, New Jersey — *10/88*

Invited Speaker and Committee Member
Drug Regulation of Novel Drug Delivery Systems
Third International Conference on Drug Absorption
Rate Control in Drug Therapy
Edinburgh, Scotland — *9/88*

** *Presented invited papers at the 13th, 17th, 19th,*
21st, 23rd, 24th, 25th, 26th and 31st
Annual International Industrial Pharmacy Symposia,
and was a Reactor Panel Member for 22nd Symposium.
Chaired panels for 24th-31st International Symposia
International Industrial Pharmacy Conference — *1974-1993*

Retinoids and Glucocorticoid Dermatology Project.
Shah, V. P., Skelly, J. P.
Cannes, France — *8/88*

Biopharmaceutic Electronic NDA's
Drug Information Association, 24th Annual Meeting
Toronto, Canada — *7/88*

Computer Assisted NDA Review
PMA/FDA Meeting
Baltimore, Maryland — *6/88*

In Vitro Release Profile of Clonidine and Scopolamine Transdermal Patches.
AAPS, Eastern Regional Meeting
Atlantic City, New Jersey — *6/88*

Therapeutic and Biopharmaceutics Evaluation of Oral Extended Release Forms.
Arbeitsgemeinschaft Fur Pharmazeutische Verfahrenstechnik Technology Seminar
Wurzburg, West Germany — *6/88*

In Vitro Methods for Topical Drug Products
Shah, V. P., and Skelly, J. P.
5th Annual Symposium of Skin Pharmacology Society
Paris, France — *5/88*

1988 Seminar Series
Topical Dissolution Characterization for Controlled Release Forms
King of Prussia, Pennsylvania — *4/88*

Oral Controlled Released Dosage Forms: Symposium on Evaluation of Controlled Released Dosage Forms
Woodcliff Lake, New Jersey — *3/88*

The Use of Topographical Analysis in Control of Controlled Release Drugs
National Organization for Drug Control
Cairo, Egypt — *10/87*

In Vitro Dissolution Testing and In Vivo Correlations
National Organization for Drug Control and Research
Cairo, Egypt — *10/87*

In Vivo-In Vitro Relationship
School of Pharmacy
Cairo University
Cairo, Egypt — *10/87*

Drug Regulation and Importance of In Vitro Dissolution
University of Alexandria;
Alexandria, Egypt — *10/87*

Pharmacokinetic Aspects of Sustained Release Products With Special Reference to FDA Requirements
Neu Ulm Conference; Neu Ulm, West Germany — *9/87*

Pharmacokinetics in Drug Development
First Annual Symposium of the Eastern Regional Group
American Association of Pharmaceutical Scientists
Atlantic City, New Jersey — *9/87*

Sponsor and Moderator.
Anti-Cancer and Ophthalmic Drugs Workshop.
American Association of Pharmaceutical Scientists.
Boston, Massachusetts *6/87*

Panelist. Targeted Drug Delivery Systems.
American Association of Pharmaceutical Scientists
2nd Meeting and Exposition; Boston, Massachusetts *6/87*

Some Considerations for Developing A Dissolution Test for Enteric Coated Erythromycin Tablets.
American Association of Pharmaceutical Science
Boston, Massachusetts *6/87*

Study of Dissolution Media for Testing Commercial ISDN CR Tablets and Capsule Forms AAPS
Boston, Massachusetts *6/87*

Influence of pH on the Dissolution Profile of Marketed Diazepam Products AAPS
Boston, Massachusetts *6/87*

Higher Agitation for Dissolution Standard Necessary for Immediate Release Products AAPS
Boston, Massachusetts *6/87*

Effect of Food on Bioavailability of Controlled Release Theophylline Products
American Association of Pharmaceutical Scientists
Washington, D. C. *6/87*

Pharmacokinetics in the Elderly
Reactor, Geriatric Drug Update - 1987.
National Institute of Health
Bethesda, Maryland *5/87*

Bioavailability/Bioequivalence -- Pharmaceutical Coating and Controlled Release Technologies Symposium.
Arnold and Marie Schwartz College of Pharmacy
Saddle Brook, New Jersey *5/87*

Bio-Pharmaceutical Requirements for Pre-Market Approval.
Global Pharmaceutical Development & Registration Symposium.
Twenty-Third Annual Meeting of the Drug Information Association.
San Francisco, California *5/87*

Controlled Release Guidelines
Biopharmaceutics Seminar
Center for Drugs
Rockville, Md. *4/87*

Evaluation of Controlled Release Dosage Forms.
Oral Controlled Release Dosage Forms Symposium
Woodcliff Lake, New Jersey *3/87*

Food Effects in New Drug Development.
Division of Biopharmaceutics and
Pharmaceutical Manufacturers Association, Workshop
Washington, D. C. — *3/87*

Regulatory Considerations in Bioavailability
Testing in USA.
Arbeitsgemeinschaft Fur Pharmazeutische Verfahrenstechnik
Wurzburg, West Germany — *2/87*

Federation Internationale Pharmaceutique
Working Group on Use of the Flow-Through System
for Dissolution Testing of Controlled Release Forms.
Frankfurt, West Germany — *2/87*

The Current Status of the Correlation and/or Predictability
of In Vitro Studies as Compared to In Vivo Studies.
FDA/Industry Workshop (w/Sandoz)
East Hanover, New Jersey — *1/87*

** *Presented Invited papers at the 7th, 8th, 9th,*
13th and 17th International Meetings of the
Controlled Release Society — *1980, 1981, 1982 1986 and 1990*

Drug Bioavailability and Bioequivalence
FDA Perspective
III Latino-American Meeting of Pharmaceutical Scientists
Montevideo, Uruguay — *12/86*

Pharmacokinetic/Regulatory Aspects of Transdermal
Drug Delivery Systems
1986 Neu Ulm Conference on Transdermal Delivery Systems
New Ulm, West Germany — *12/86*

Effect of pH on the In Vitro Dissolution Rate of
Diazepam Tablets USP
AAPS. Washington, D. C. — *11/86*

Development of a Dissolution Test for USP
Conjugated Estrogens Tablets.
AAPS. Washington, D. C. — *11/86*

Principles and Practices of In Vitro
Percutaneous Penetration Studies
Transdermal Workshop -- AAPS and FDA; Washington, D. C. — *11/86*

Bioavailability of Topical Hydrocortisone Acetate
In Vivo-In Vitro Correlations
AAPS: Washington, D. C. — *11/86*

Standardization of Dissolution Specifications
AAPS. Washington, D. C. — *11/86*

A Novel Approach for Determining In Vitro
Drug Release Rate for Creams
AAPS: Washington, D. C. — *11/86*

Analysis of In Vitro Dissolution of Whole vs. Halved
Controlled Release Theophyline Tablets
AAPS - Washington, D. C. — *11/86*

Comparative In Vitro Release Profiles of Marketed Nitroglycerin Patches by Different Dissolution Methods
American Association of Pharmaceutical Scientists
Washington, D. C. *11/86*

An Animal Model for Bioavailability Study on Controlled-Release Formulations Under Influence of Food
American Association of Pharmaceutical Scientists
Washington, D. C. *11/86*

Evaluation of Dissolution Methodology for Ibuprofen Tablets
American Association of Pharmaceutical Scientists
Washington, D. C. *11/86*

FDA Biopharmaceutics Program
Japan Pharmaceutical Manufacturers Association
Rockville, Maryland *10/86*

Evaluation of Controlled Release Dosage Forms
Eastern Regulatory Pharmaceutical Discussion Group of the AAPs and Hudson Valley AAPS Group
Montvale, New Jersey *9/86*

Topographical Dissolution Characterization of Controlled Release Dosage Forms and Their Relationship to In Vivo Drug Absorption
Thirteenth International Symposium on Controlled Release of Bioactive Materials
Norfolk, Virginia *8/86*

USA Regulatory Considerations in Bioavailability Testing
Fifth International Symposium on Bioavailability
Third World Conference on Clinical Pharmacology and Therapeutics
Gothenburg, Sweden *7/86*

Panalist: Discussion Population Pharmacokinetics, Application to Drug Development and Utilization.
University of Pittsburgh
Pittsburgh, Pennsylvania *5/86*

Interphex- Dissolution Tests for Oral Extended Release Products and Drug Release Tests for Transdermals
Interphex 1986
New York, N. Y. *4/86*

Novel Drug Delivery Systems
Association of Official Analytical chemists
Seattle, Washington *4/86*

Biopharmaceutics in Drug Regulations
University of Saskatchewan
Colloge of Pharmacy
Saskatoon, Saskatchewan, Canada *11/85*

International Symposium on Drug Analysis: Current Challenges. Satellite Symposium
45th International Congress.
Sponsored by Health and Welfare Canada
Ottawa, Ontario, Canada *11/85*

Biopharmaceutics in NDA/ANDA submission.
Drug Information Association Workshop
Hilton Head, South Carolina — *11/85*

Preparation of High Purity Reference Standards of Nitroglycerin Dinitration Products and the Development of Complementary HPLC-GC Analyses
Academy of Pharmaceutical Sciences National Meeting
Minneapolis, Minnesota — *10/85*

The Analysis of Prednisolone Acetate and Related Corticoids in Swine Plasma by Reversed Phase HPLC.
Academy of Pharmaceutical Sciences National Meeting
Minneapolis, Minnesota — *10/85*

The Effects of Food on Absorption of Controlled Release
Academy of Pharmaceutical Sciences
Minneapolis, Minnesota — *10/85*

In Vitro Methodology: Relation to In Vivo Chemists
Seminar, Center for Drug Evaluation and Research
Rockville, Maryland — *10/85*

Dissolution of Transdermal Patches
Federation International Pharmaceutique
Montreal, Canada — *6/85*

Forty-fifth International Congress of Pharmaceutical Sciences of Federation Internationale Pharmaceutique
Montreal, Quebec, Canada — *9/85*

Second Control Release Specialty Chemical Conference
Pittsburgh, Pennsylvania — *7/85*

Pharmaceutical Manufacturers Association Workshop.
Drug Metabolism Subsection Workshop
Bethesda, Maryland — *5/85*

Biopharmaceutic Considerations in Design and Evaluation of Novel Drug Delivery Systems.
University of New York at Bufflo (SUNY)
Buffalo, New York — *4/85*

Biopharmaceutic Considerations in Designing and Evalation of Novel Drug Delivery Systems
University of Buffalo; Buffalo, New York — *4/85*

Dossier D'Autorisationde Mise Sur Le Marche
Assoc. Pour Le Develop. De La Pharmacokinetique
Montpellier, France — *3/85*

Novel In Vitro Technique for Assuring Bioequivalence for Controlled Release Dosage Forms
Assoc. of Clin. Pharmacology
San Antonio, Texas — *3/85*

Biopharmaceutic Considerations in Geriatric Drug Research
Drug Information Association
Bethesda, Maryland — *3/85*

Novel Drug Delivery Systems
Twenty-fourth International Industrial Pharmacy Conference
Austin, Texas — *2/85*

KINPAK - Evaluation of New Computer System for Organizing Pharmacokinetic Data.
Rockville, Maryland — *11/84*

FDA Guidelines for Controlled Release Dosage Forms
Skelly, J. P. and Viswanathan, C. T.
R-EXPO Industrial Pharmacy
New York, New York — *10/84*

Panel Member -- Toxicokinetics
Pharmaceutical Manufacturers Association
Drug Metabolism Subsection
Philadelphia, Pennsylvania — *9/84*

Pharmacokinetic Differences in the Elderly.
Workshop on Pharmacokinetics in the Elderly
American Soc. for Clinical Pharmacology and Therapeutics
Rockville, Maryland — *9/84*

Role of Metabolite: FDA Point of View
Viswanathan, C. T., and Skelly, J. P.
Academy of Pharmaceutical Sciences
Philadelphia, Pennsylvania — *9/84*

Transdermal Dosage Forms - Regulatory Point of View
Academy of Pharmaceutical Sciences
Somerset, New Jersey — *9/84*

The Impact of Biopharmaceutic Research on The Regulatory Process
American Chemical Society Symposium
Philadelphia, Pennsylvania — *8/84*

OTC Combination Products
Pharmacokinetics and Biopharmaceutics, Advanced Course
Bad Lauderburg, Germany — *6/84*

Pharmacokinetics and Controlled Release Drugs
Pharmacokinetics and Biopharmaceutics, Advanced Course,
Bad Lauderburg, Germany — *6/84*

Controlled Release Drugs
University of Manchester
Manchester, England — *6/84*

Pharmacokinetic Studies in Elderly Subjects and Other Special Populations.
Controlled Release Dosage Forms — *5/84*

Association of Official Analytical Chemists
Philadelphia, Pennsylvania — *5/84*

Basic Pharmaceutics Pharmacodynamic Drug Disposition
Section of the 1984 American Pharmaceutical Association
Academy of Pharmaceutical Sciences
Midwest Regional Meeting
Chicago, Illinois — *4/84*

Regulatory Perspectives
Pharmacokinetic Considerations in Drug Studies
Twenty-third Annual International Industrial
Pharmacy Conference
Austin, Texas — *2/84*

Biopharmaceutic Considerations in Designing and
Evaluating Novel Drug Delivery Systems
Thirty-fifth National Meeting of the American
Pharmaceutical Association
Academy of Pharmaceutical Sciences (short course)
Miami Beach, Florida — *11/83*

Guidelines Considerations in Conducting
Pharmacokinetic Studies
Symposium on Role of Clinical Pharmacokinetics
in Drug Development and Therapy
Miami, Florida — *11/83*

FDA Perspective
Proposed USP Policy on Modified Release Dosage Forms.
Academy of Pharmaceutical Science
Miami, Florida — *11/83*

Controlled Release Drug Products
School of Pharmacy, Rutgers University
Piscataway, New Jersey — *11/83*

Issues of Bioavailability and Bioequivalence.
II Reunion Latino Americana de Ciencias Farmaceuticas
Colegio De Quimico-Farmaceuticos De Chile
Santiago, Chile — *11/83*

Correlation and/or Predictability of In Vitro
Studies to In Vivo Studies
Industry - FDA Workshop
East Hanover, New Jersey — *10/83*

Biopharmaceutic Issues Related to Controlled
Release Drug Products.
Purdue University Management Conference
West Lafayette, Indiana — *9/83*

Regulatory Considerations for Controlled Release
Drug Products.
Twenty-fifth Annual National Industrial Pharmaceutical
Research Conference
University of Wisconsin
Lake Delton, Wisconsin — *6/83*

Clinical Pharmacokinetics
Third Workshop on Clinical Pharmacokinetics
Drug Metabolism Managers Group
Washington, D. C. *3/83*

Industrial Issues: Reactor Panalist
Twenty-second Annual International Industrial Pharmacy Symposium
Austin, Texas *2/83*

Panelist: "What It Takes to Make a Successful Controlled Release Pharmaceutical Product".
Ninth International Symposium on Controlled Release of Bioactive Material
Fort Lauderdale, Florida *7/82*

Development of Biopharmaceutic Master Files
Twenty-first Annual International Industrial Pharmacy Conference
Lakeway Inn, Austin, Texas *2/82*

Drug Bioavailability.
Second Workshop on Clinical Pharmacokinetics
Drug Metabolism Managers Group
Washington, D. C. *1/82*

Sustained Release Technology Forum:
Regulatory Agency's Viewpoint.
Entomological Society of America Meeting
San Diego, California *11/81*

Guidelines for Evaluating the Bioavailability of Controlled Release Dosage Forms.
Eighth International Symposium on Controlled Release of Bioactive Material
Fort Lauderdale, Florida *7/81*

Isotope Labeling and Mass Spectroscopy in Glucocorticoid Bioavailability Studies.
Academy of Pharmaceutical Sciences
Midwest Regional Meeting
Chicago, Illinois *5/81*

Preclearance of Generics - <u>Yes or No!</u>
"An FDA Perspective."
Austin, Texas *2/81*

Drug Metabolism Managers Group Workshop in Clincial Pharmacokinetics
Washington, D. C. *1/81*

The FDA and the Bioequivalence of Drug Products
The 2nd Congress of Chemistry on the North American Continent
Las Vegas, Nevada *8/80*

The FDA and Controlled Release Delivery Systems
Biopharmaceutics Perspective
Seventh International Symposium Controlled Release Society
Fort Lauderdale, Florida 7/80

FDA Representative
Revson Conference of Frontiers in the Health Sciences:
Implications of Environmental/Genetic Interactions.
National Academy of Sciences, Institute of Medicine
Washington, D.C. 7/80

Dissolution as a Predictor of Bioavailability
Research Society of America/Sigma Xi
Rockville, Maryland 3/79

Dissolution Proficiency Testing
Seventeenth Annual International Industrial
Pharmacy Conference
Austin, Texas 2/79

FDA Policy in Regard to Dissolution Technology
Pernarowski Memorial Seminar
Academy of Pharmaceutical Sciences
Montreal, Canada 5/78

Role of Dissolution in Assessing and Predicting
Drug Bioequivalence
Mid-West Regional Academy of Pharmaceutical Sciences,
Chicago, Illinois 4/78

FDA Policy in Regard to Dissolution Technology
Pernarowski Memorial Seminar
Academy of Pharmaceutical Sciences
Montreal, Canada 5/78

Bioequivalence and Issues of Drug Interchangeability
Boards and Colleges of Pharmacy, Region II
Silver Spring, Maryland 10/77

Implementation of the Bioavailability and
Bioequivalence Regulations
Management Science Conference for the Pharmaceutical Industry
Purdue University
West Lafayette, Indiana 9/77

Maximum Allowable Cost Advisory Committee
HEW Portal Building
Washington, D. C. 9/77

Pharmacokinetic and Metabolic Studies of
Chlorozotocin in Mice
Mhatre, R. Schein, P., Skelly, J., Waravdekar, V.
American Association of Cancer Research
Denver, Colorado 5/77

Bioavailability, Bioequivalence and Related Issues
Bureau of Drugs Seminar
Rockville, Maryland 3/77

Proficiency Testing: Guidelines for Carrying Out Dissolution Tests Which Are Classified as In Vitro Bioequivalence Requirements
Pharmaceutical Manufacturers Association
Shoreham Americana Hotel
Washington, D. C. 3/77

Bioavailability Update
American Academy of Pediatrics, Committee on Drugs
Washington, D. C. 3/77

FDA Representative
Parenteral Amino Acids
American Academy of Pediatrics
Bethesda, Maryland 6/76

Bioavailability and Bioequivalence
American College of Clinical Pharmacology
Philadelphia, Pennsylvania 4/76

Problems Encountered in the Determination of Drug Bioavailability
Bureau of Drugs Chemists Seminar
Rockville, Maryland 3/76

FDA Panelist
Pharmaceutical Manufacturers Association Medical Section, Interim Meeting
Washington, D. C. 11/75

FDA Representative - Bioavailability Issues in Pediatrics
American Academy of Pediatrics, Committee on Drugs
Washington, D. C. 10/75

FDA and Bioavailability/Bioequivalency Regulations
San Francisco Bay Area Pharmaceutical Discussion Group
San Francisco, California 5/75

Pharmaceutical Update-FDA's Bioavailability Requirements
American Medical Writers Asssociation
Los Angeles, California 10/74

FDA Bioavailability Guidelines and Policies
West Virginia U. Pharmacy Institute
Morgantown, West Virginia 6/74

Guidelines to be Employed for Antibiotic Bioavailability Studies
FDA - Industrial Conference on Antibiotic Bioavailability
Rockville, Maryland 6/74

Drug Bioavailability, Time Release, In Vitro Testing
1974 FDA Field Drug Workshop
Philadelphia, Pennsylvania — *5/74*

New FDA Digoxin Regulations
Association of Food and Drug Officials
Lancaster, Pennsylvania — *5/74*

Consumer Issues Involved in the Generic Versus Brand Name Drug Debate: "Federal Activities and Initiatives".
Council of State Governments (Joint Session Eastern and Southern Regional Conferences).
Atlanta, Georgia — *4/74*

Bioavailability Policies and Guidelines
Thirteenth Annual International Industrial Pharmacy Conference
Austin, Texas — *2/74*

Bioavailability and the FDA
57th Annual Conference of the Central Atlantic States Association of Food and Drug Officials
College Park, Maryland — *5/73*

FDA Representative
National Workshop on Digoxin Bioavailability
Research Triangle, North Carolina — *3/73*

Collagen and Elastin Metabolism in Induced Atherosclerosis
Middle Atlantic Regional Meeting - American Chemical Society
Baltimore, Maryland — *2/71*

Bioequivalence of Phenylbutazone
Division of Metabolic Endocrine Drug Product
Bureau of Medicine
Rockville, Maryland — *9/70*

INTERNATIONAL MEETINGS:

Scale-Up & Post Approval Changes
Immediate Release & Modified Release Dosage Forms
Second Pharmaceutical Sciences Conference
Assiut University
Assiut, Egypt — *3/2000*

MDS Pharmacokinetics Symposium
Lyon, France — *3/2000*

In-Vivo/In Vitro Correlations *Second Pharmaceutical Sciences Conference* *Assiut University* *Assiut Egypt*	*3/2000*
Moderator *Drug Delivery* *Phoenix International Symposium* *Montreal, Canada*	*6/99*
Drug Approval! Future Aspects of FDA *Quo Vadis Medicamentum* *Bobenheim, Germany*	*4/97*
Rapporteur, BioInternational '94 *Bioequivalence: Quality Control and Therapeutic Surrogate* *BioInternational '94* *Munich, Germany*	*6/94*
Potential Effects of Healthcare Reform on the Pharmaceutical Industry *Phoenix International Life Sciences:* *Fifth Annual Symposium* *Montreal, Quebec, Canada*	*5/94*
Evaluation of Regulatory Guidelines Based on Case Histories *Second International Conference on Controlled Release Dosage Forms* *Zurich, Switzerland*	*3/94*
In Vitro/In Vivo Correlations in Biopharmaceutics: Scientific & Regulatory Implications *5th European Congress Biopharmaceutics and Pharmacokinetics* *Brussels, Belgium*	*4/93*
How to Define a Panel of Volunteers *3rd Regipharm Symposium* *From Human Microsomes to Multinational Registration Files:* *An Integrated Approach to Human Pharmacokinetics Development* *Brussels, Belgium*	*10/92*
Regulatory Assessment of Controlled Drug Delivery *Pharmacy World Congress '92* *Federation Internationale Pharmaceutique,* *Ipharmax and* *National Congress of French Pharmacists* *Lyon, France*	*1992*

Conference Committee Member, BioInternational '92
Bioavailability/Bioequivalence & Pharmacokinectic Studies
Panel Co-Chair and Panelist on
'Bioequivalence of Highly Variable Drugs II'
Bad Homberg/Frankfort, Germany **1992**

Plenary Session Moderator & Panalist
International Open Conference
USP, HPB, & FDA
Toronto, Canada **1992**

Case Histories:
First International Conference
Oral Controlled Dosage Forms
Berlin, Germany **1992**

Analytical Methods Validation for
Bioavailability and Bioequivalence Studies
Second Symposium on Drug Bioavailability
Santiago, Chile **1991**

Co-Chairman: Bioavailability and Bioequivalence and World Standards
Pharmacy World Congress - FIP;
Wash. D. C. **1991**

Regulatory Requirements for Quality Control
and Assessment of Bioavailability and Bioequivalence
Pharmacy World Congress - FIP
Washington, D. C. **1991**

Analytical Methods Validation and Stability Studies
Australian Pharmaceutical Science Association
Adelaide, Australia **1991**

Symposium Summation and Commentary
Australian Pharmaceutical Science Association
Adelaide, Australia **1991**

The Research Program
Center for Drug Evaluation & Research
Therapeutic Goods Administration
Canberra, Australia **1991**

The United States Drug Approval Process
"Sea Change or Temporary Turbulance"
Therapeutic Goods Administration
Canberra, Australia **1991**

Drug Registration in Europe:
Update and Trends for the Future
Brussels, Belgium **1990**

European Commission Ad Hoc Committee
on the Definition of Bioavailability:
Federation Internationale Pharmaceutique
Satellite Conference
Munich, Germany — *1989*

BioInternational '89
Evaluation of Bioavailability Data
Ontario, Canada — *1989*

** *National Institute of Hygenic Sciences Seminars*
Evaluation of Dosage Form Design
Tokyo, Osaka and Kyoto, Japan — *11/89*

International Symposium on Drug Bioavailability
Universidad De Chile
Santiago, Chile — *10/89*

Invited Speaker and Committee Member
Drug Regulation on Novel Drug Delivery Systems
Second International Conference on Drug Absorption
Rate Control in Drug Therapy
Edinburgh, Scotland — *9/88*

Retinoids and Dermatology
Project of Glucocorticoids
Cannes, France — *8/88*

Twenty-Fourth Annual Meeting, Drug Information Association
Biopharmaceutics Electronic NDA's
Toronto, Canada — *7/88*

Intern'l Association for Pharmaceutical Technology Seminar
Therapeutic and Biopharmaceutic Evaluation of
Oral Extended Release Forms
Wurzburg, West Germany — *6/88*

In Vitro Methods for Topical Drug Products
5th Annual Symposium of Skin Pharmacology Society
Paris, France — *5/88*

Pharmacokinetic Aspects of Sustained Release Products
with Special Reference to FDA Requirements
New Ulm, West Germany — *9/87*

World Health Organization
In Vitro Dissolution Testing and In Vivo Correlations
Cairo, Egypt — *9/87*

** *Multiple presentations*

Federation Internationale Pharmaceutique
Working Group on Use of Flow-Through System
for Dissolution Testing of Controlled Release Forms
Frankfurt, West Germany — *2/87*

USA Regulatory Considerations in Bioavailability Testing
International Association for Pharmaceutical Technology
Wurzburg, West Germany — *2/87*

Presented Invited papers at the 7th, 8th, 9th, and 13th
International Meetings of the Controlled Release Society — *1980, 1981, 1982 and 1986*

Fifth International Symposium on Bioavailability
Third World Conference on Clinical Pharmacology
and Therapeutics
Gothenburg, Sweden — *July/Aug.,1986*

Drug Bioavailability Bioequivalence, FDA Perspective
Third Latino American Meeting of Pharmaceutical Science
Montevideo, Uruguay — *11/86*

Pharmacokinetic/Regulatory Aspects of Transdermal Drug Delivery Systems
1986 Neu Ulm Conference on Transdermal Delivery Systems
New Ulm, West Germany — *12/86*

Dossier D'Autorisationde Mise Sur Le Marche
Assoc. Pour Le develop. De La Pharmacokinetique
Montpellier, France — *3/85*

Biopharmaceutics in Drug Regulation
College of Pharmacy, University of Saskatchewan — *3/85*

45th International Congress of Pharmaceutical Sciences, FIP
Montreal, Quebec, Canada — *9/85*

Dissolution of Transdermal Patches
Montreal, Canada — *9/85*

Symposium on Drug Analysis: Current Challenges.
Satellite Symposium of the 45th International Congress
Sponsored by Health and Welfare Canada
Ottawa, Ontario, Canada — *9/85*

Seminar to Drug Directorate Staff, HPB Health and Welfare
Ottawa, Ontario, Canada — *9/85*

Faculty Member -- Advanced Pharmacokinetics
Pharmacokinetics & /Biopharmaceutics, Advanced Course
Bad Lauderburg, Germany — *6/84*

Controlled Release Drugs
University of Manchester
Manchester, England *6/84*

Issues of Bioavailability and Bioequivalence
II Reunion Latino Americana de Ciencias Farmaceuticas
Colegio De Quimico-Farmaceuticos De Chile
Santiago, Chile *11/83*

Invited Speaker (personal invitation)
Second International Conference on Drug Absorption
Rate Control in Drug Therapy
Edinburgh, Scotland (Unable to go because of lack of funds) *9/83*

Invited Speaker and Invited Workshop Panalist
Federation Internationale Pharmaceutique
Montreaux, Switzerland *9/83*

Modest Pernarowski Memorial Seminar
International Meeting of the Academy of Pharmaceutical Sciences
Montreal, Canada *10/78*

PUBLICATIONS:

Van Buskirk, Zenie, F.,G., Layloff, T., Skelly, J.P.; Paperless Laboratories - They're Inevitable! The Paperless Laboratory - Finally A Reality; American Pharmaceutical Review, Page 100-106. December, 2002.

Skelly, J.P.: Scale-Up and Post Approval Changes (SUPAC). Encyclopedia of Pharmaceutical Technology. Marcel Dekker, N.Y. 2002

Jiang, M., Qureshi, S. A., Midha, K., & Skelly, J. P.: In Vitro Evaluation of Percutaneious Absorption of an Acyclover Product. Using Intact and Taped-Stripped Human Skin. Journal of Pharm. & Pharm. Sci. Jan., 99

Endrenyi, L., Amidon, G. L., Midha, K., & Skelly, J. P.: Individual Bioequivalence: Attractive in Principle, Difficult in Practice. Pharm. Res. 15(9) 1321-1325: 1998

Skelly, J.P.: Drug Approval - Future Aspects of FDA in Proceedings "Quo Vadis Medicamentum" Institute Fur Klenische Pharmakologic In Methods & Findings in Expermental Clincal Pharmacology. 20(6): 1998

Crison,J., Shah, V. P., Skelly, J. P., Amidon, G.L.: Drug Dissolution into Micellar Solutions: Development of a Convective Diffusion Model and Comparison to the Film Equilibrium Model with Application to Surfactant-Facilitated Dissolution of Carbamazepine. J. Pharm. Sci. pages 1005-1011; Sept.; 85(9), 1996.

Skelly, J. P., Van Buskirk, G. A., Arbit, H. M., Amidon, G. L., Augsburger, L., Barr, W. H., Berge, S., Clevenger, J., Dighe, S., Fawzi, M., Fox, D., Gonzalez, M. A., Gray, A., Porter, S., Robinson, J., Savello, D. R., Schwartz, P., Schwartz, J. B., & Shah, V. P.: Scale-Up of Oral Extended-Release Dosage Forms. Pharmaceutical Technology Pages 46-54, May 1995.

Shah, V. P., Noory, A., Noory, C., McCullough, B., Clarke, S., Everett, R., Noviosky, H., Srinivason, B. N., Fortman, D., & Skelly, J. P.: In Vitro Dissolution of Sparingly Water-Soluble Drug Dosage Forms. Intl. Jr. of Pharm. 125:99-106: 1995

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Development of an HPLC Method for Analysis of Estradiol, Estrogens, and Conjugated Estrogens in Serum Samples, Su, S. Y., Shiu, G. K., Simmons, J. E., Viswanathan, C. T. & Skelly, J. P., AAPS 4th Annual National Meeting, Atlanta, Georgia, October 1989.

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Effects of Moisture on Dissolution of Carbamazepine Tablets, Wang, J. T., Ong-Chen, T., Shiu, G. K., Viswanathan, C. T., and skelly, J. P. AAPS 4th National Meeting, Atlanta, Georgia, October 1989.

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Evaluation of Flow Through and Rotating Dialysis Cell Methods for In-Vitro Testing of Suppositories, Shiu, G. K., Lootvoet, G., Worsley, W., Skelly, J. P., AAPS Annual Meeting, Atlanta, Georgia, 1989.

Effects of Moisture on Dissolution of Carbamazepine Tablets. Wang, J. T., Ong-Chen, T., Shiu, G. K., Viswanathan, C. T., & Skelly, J. P. FDA Science Expo 1989

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Development of an HPLC Method for Analysis of Estradiol, Estrogens, and Conjugated Estrogens in Serum Samples. Su, S. Y., Shiu, G.K., Simmons, J. E., Viswanathan, C. T., & Skelly, J. P. FDA Science Expo 1989

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An In Vitro study of Food-Drug Interactions in Sustained-Release Propranolol Products. Shiu, G., El-Arini, S., & Skelly, J. P. AAPS Annual Meeting, Orlando, Florida 1988.

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Dissolution Testing of Oral Contraceptive Combination Tablets, Nguyen, H. T., Worsley, W. N., Shiu, G. K., and Skelly, J. P., AAPS Annual Meeting, Orlando, Florida, 1988.

Effect of Surfactants on the Dissolution of Very Slightly Water Soluble Drugs,Wang, J., Worsley, W., Shiu, G., Skelly, J. P., AAPS Annual Meeting, Orlando, Florida, 1988.

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J. P. Skelly, P. Hepp, C. T. Viswanathan
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Skelly, J. P.

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Anti-Convulsant Drug Products
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FDA, Rockville, Maryland, February 8, 1977.*

J. P. Skelly
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as In Vitro Bioequivalence Requirements
Office of the Heaing Clerk, Rockville, Maryland, March 15, 1977.

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Guidelines for In Vivo and In Vitro Dissolution Testing
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Guidelines for Conducting Physiologic Bioavailability
Studies on Conventional Release, Chewable, and Controlled
Release Anti-Anginal Drug Products
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J. P. Skelly, H. Malinowski, V. Shah, S. Dighe
Collaborators: C. Garcia, L. Pogliaro, A. Till, S. Joslyn,
M. Sylvestri, R. Ball, R. S. Proctor, J. Michalko,
K. Grant, R. Maddox, W. Gary, R. Varbel, K. Killeen
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Office of the Hearing Clerk
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J. P. Skelly, C. M. Ise, V. Shah, S. V. Dighe
Procainamide Drug Bioavailability Monograph

OUTSIDE ACTIVITES

Chair: Nominations Committee;
Board of Directors, Mount Vernon Yacht Club. 2002 & 2003
Past Commodore, Mount Vernon Yacht Club: 2000-Present
Charter Member FDA Alumni: 2001-Present
Member Rules and By-Laws Committee, MVYC 2000-2003
Commodore; Mt. Vernon Yacht Club: November, 1998 to 2000
CEO, Mt Vernon Yacht Club: November, 1998 to 2000
Member of Board of Directors, Mt. Vernon Yacht Club: 1997 to 2000
Judge, Fairfax County School Science Fair; 1999-2002

Mt. Vernon Yacht Club, 1st Place; Craney Island Sailboat Race: August, 1998
Yacht Haven Civic Association; 1980-1994 and 1996 to Present
Marina Bay (Squantum, Mass.) Civic Association; 1995-1997
Presenter, City Council, Quincy, Mass. 1996-1997
Friends of Mt. Vernon Yacht Club; 1992-1996
Neighborhood Friends of Mt. Vernon; 1992-Present
Developed & Taught Course on Sailboat Racing, MVYC Sail Fleet 1992
Church Member (including church committees)
Co Chair Millennium Committee, Mt. Vernon Yacht Club 1991
Carnegie Mellon, Senior Executive Seminar Committee 1985-1992
Santa Claus - MVYC and Yacht Haven 1980-Present
Member Mount Vernon Yacht Club (MVYC) 1977-Present
MVYC Sail Racing Fleet (Spring and Autumn Series plus Various Regattas) 1977-Present
Owner/Manager, American Manaagement (Community Pool Management Firm) 1978-1987
SOME: SO OTHERS MAY EAT; Soup Kitchen; Washington, D. C. 1982-1990
MVYC Pool Committee 1978-1984
United States Coast Guard Auxiliary Flotilla 14-4, 1983
Alternate MVYC Representative Chesapeake Bay Yacht Club Association 1981-1991
Wayne State University Alumni Association, Capitol Hill Meeting Board 1969-1981
Wayne State University Alumni Association, Washington, D. C. Chapter 1969-1984
Member West Springfield Civic Association 1976-1979
Community Representative to the Northern Virginia; Swim League 1970-1975
Member Kings Park Civic Association 1969-1975
Block Captain, Kings Park Civic Association Annual Burke Volunteer Fire Department Fund Drive 1970-1974
Past Chairman, Kings Park Civic Association Subcommittee on Planned Land Use in Fairfax County (PLUS) 1973-1974
Past Member Springfield Magisterial District PLUS Group
Official N.V.S.L. Competitive Swim Meets (Regular Season, Winter Swim, All Star Events)
1. *Judge 1969-1971*
2. *Timer 1970-1974*
3. *Chief Timer 1972-1977*
4. *Stroke and Turn Judge 1974-1977*

Official DCCL Competitive Swim Meets (Regular Season and All Star Events)
1. *Stroke and Turn Judge 1977-1979*
2. *Assistant Chief Timer 1978*
   All Star Relays 1979
3. *Referee 1979-1985*

MVYC Dock Master 'D' Dock, 1978-1982
Royal Pool Association, Board of Directors 1970-1971, 1971-1972
Manager Pool Concession Stand 1970-1972
Manager Royal Combined Winter Swim Teams 1970-1971 and 1971-1972
Braddock Road Boys Club - Assistant Coach Soccer Team - 1973 & 1974
Past Member Kings Park & Kings Glen Elementary, Holmes Intermediate and Robinson High school PTA's
Past Member Washington Irving Intermediate, Drake High School, and Lake Braddock High School PTA's
Past Member West Springfield High School PTA
Active participant in numerous PTA Fun Fairs, etc.
Chaired Several Interfaith Church Related Race Relationship Groups 1966-1968 (Project Commitment and Project Hope - Detroit, Michigan

Member; Conference on Law, Order, and the White Backlash; Detroit, Mich. 1966

FACULTY MEMBER COLLEGE OF PHARMACY
UNIVERSITY OF CINCINNATI
AND
CONTINUING EDUCATION PROGRAM AND SHORT COURSES

SHORT COURSES:
Center for Professional Advancement: SUPAC
Biannually in New Jersey and in Amsterdam.(1996-Present).

SUPAC - Short Course
AAPS Annual Meeting; New Orleans, Louisianna: 1999

Bioequivalence and/or In Vitro Testing in Lieu of Clinical Efficacy
University of Cincinnati
Cincinnati, Ohio: 11/12/98

Scale-Up and Post Approval Changes
Solid Oral and Semi-Solid
Percutaneous Dosage Forms
University of Cincinnati
Cincinnati, Ohio: 11/12/98

Regulatory and Industrial Considerations, and
Analytical Requirements for SUPAC
Institute for Applied Pharmaceutical Science
East Brunswick, New Jersey: 5/18/98

Regulatory Documentation and Testing
Requirements for SUPAC
Institute for Applied Pharmaceutical Science
East Brunswick, New Jersey: 5/18/98

Regulatory Requirement for Approval of
Generic Percutaneous Dosage Forms
Institute for Applied Pharmaceutical Science
East Brunswick, New Jersey: 5/19/98

In-Vivo - In Vitro Correlations
College of Pharmacy
University of Connecticut
Storrs, Conneticut: 9/97

FDA Requirements for Scale-Up, Site Transfer, and Formulation Changes for
Immediate Release and Controlled Release Dosage Forms
University of Cincinnati
Cincinnati, Ohio: 11/96

Dermatopharmaceutics and Changing Requirements for
Pharmacokinetic and Pharmocodynamic Studies for Testing
Topical Semi-Solid Dosage Forms
University of Cincinnati
Cincinnati, Ohio: 11/96

Drug Bioavailability, Bioequivalence Dissolution: & Biopharmaceutics
National Drug Manufacturing and Quality Control
FDA Field Inspectors Training Course
DHHS - FDA - Univ. of Cincinnati
Newark, New Jersey 8/96

Individual Bioequivalence, and Highly Variable Drugs
University of Cincinnati
Cincinnati, Ohio: 10/95

Issues at The Cutting Edge of Science
Individual Bioequivalence (IBE) vs Average Bioequivalence
Cincinnati, Ohio: 10/95

In-Vitro/In-Vivo Correlations in Biopharmaceutics:
"Scientific & Regulatory Considerations"
University of Cincinnati
Cincinnati,Ohio: 9/93

Batch size Scale-Up of Solid Oral Dosage Forms
University of Cincinnati
Cincinnati, Ohio: 9/93

Transdermal Drug Delivery
Professional Seminar Institute
Ramsey, New Jersey 1990

Controlled Release Drugs
Professional Seminar Institute
Baweja, R., and Skelly, J. P.
Ramsey, New Jersey 1989

Oral Controlled Release Drugs
Professional Seminar Institute
Ramsey, New Jersey 1989

In Vitro Dissolution Testing &
In Vivo Correlations
School of Pharmacy
Cairo University
Cairo, Egypt 10/87

Drug Regulation and the
Importance of In Vitro Dissolution
University of Alexandria
Alexandria, Egypt 10/87

Bioavailability/Bioequivalence
Pharmaceutical Coating
and Controlled Release Technologies Symposium.
Sponsored by Arnold and Marie Schwartz College of Pharmacy
Saddle Brook, New Jersey May 1987

Oral Controlled Release Drugs
Professional Seminar Institute
Ramsey, New Jersey 1987

Biopharmaceutic Perspective
College of Pharmacy
University of Kentucky
Lexington, Kentucky November 1986

Biopharmaceutics in Drug Regulations
University of Saskatchewan
College of Pharmacy
Saskatoon, Canada 1985

Biopharmaceutic Considerations
in Design and Evaluation of
Novel Drug Delivery Systems
University of New York at Buffalo
Buffalo, New York 1985

Postgraduate Course in Drug Development
Clinical Pharmacology, and Regulation
The University of Rochester
School of Medicine and Dentistry
Rochester, New York 1985

Biopharmaceutics and Prescription Drug Labeling
Ciba Geigy Pharmacy Intern Program
Rockville, Maryland 1984

Advanced Pharmacokinetics
Frei Universitat Berlin
West Berlin, Germany May, 1984

Controlled Release Drug Products
College of Pharmacy
University of Manchester
Manchester, England May, 1984

Biopharmaceutics and Prescription Drug Labeling
Ciba Geigy Corporation Pharmacy Intern Program
Rockville, Maryland 1983

Biopharmaceutic Considerations
in Designing and Evaluating
Novel Drug Delivery Systems
Short Course: Academy Pharmaceutical Sciences
November 1983

Biopharmaceutics and Prescription Drug Labeling
Ciba Geigy Corporation Pharmacy Intern Program
Rockville, Maryland 1982

Bioavailability and Product Selection
College of Pharmacy
University of Utah
Salt Lake City, Utah, February 13, 1977

Drug Equivalence and Drug Substitution
Academy of Family Physicians
Continuing Education
New Carrollton, Maryland, May 21, 1977

Role of the FDA in Bioequivalence
Rhode Island Pharmacy Association
and Univeristy of Rhode Island
Providence, Rhode Island June 2, 1976

FDA Bioavailability Guidelines and Policies Pharmacy Institute
West Virginia University
On Bioavailability for the Practicing Pharmacist
Morgantown, West Virginia June 4, 1974

ADDITIONAL TRAINING

Public Relations Training for Corporate Officials
Facing a Hostile Enviroment Copley
Boston, Massacheussetts. 1996

SES Senior Executive Leadership Forum
Washington, D. C. 1991

Tutorial on Communications and Public Speaking
Skills for Managers and Technical Personnel
San Francisco, California May 1987

Executive Excellence Program
Federal Executive Institute
Charlottesville, Virginia May - July 1986

Leadership - 'When the Heat's On'
Daniel Management Center
Washington, D. C. November 1986

Giving and Taking Criticism and Managing Anger
Washington, D. C. December 1986

The One Minute Manager
Washington, D. C. December 1986

Senior Executive Seminar
Carnegie Mellon University
School of Urban and Public Affairs
Pittsburgh, Pennsylvania April-June 1985

Constructive Resolution of Conflict
Office of Personnel Management
Washington, D. C. July 1985

Center for Drugs & Biologics Course
Prevention of Sexual Harassment
August 1984

Negotiating Effectively
PHS Executive Seminar Series
Washington, D. C. 1983

HHS Course on Human Resource Management Training
on Employment of Disabled Individuals
Bethesda, Maryland 1983

Sexual Harassment for Management
Parklawn Training Institute -
Rockville, Maryland 1982

Systems Design for Management
Parklawn Training Institute
Rockville, Maryland 1982

Strategic Management
Management of Complex Systems
Managing Shrinking Resources
The Politics of Change
PHS Executive Seminar Series
Gaithersburg, Maryland 1982

HHS Department Budgeting Process
Health & Human Services Building
Washington, D. C. 1981

Experimental Design and Statistics
Parklawn Training Institute
Rockville, Maryland 1980

Advanced Project Officer Course
Parklawn Training Institute
Manassas, Virginia 1980

Parklawn Training Institute -
Rockville, Maryland 1980
Power and Influence

Interactive Fortran IV 7 TSO - Computer Lab
Parklawn Training Institute
Rockville, Maryland 1977

Budgeting for Managers
Parklawn Training Institute
Rockville, Maryland 1976

Supervisory Management
Parklawn Training Institute
Rockville, Maryland 1976

Project Officers EEO Training
Parklawn Training Institute
Rockville, Maryland 1976

Managerial Effectiveness at the Mid Level
Civil Service Commission
Washington, D. C. 1976

Pharmacokinetics and Biopharmaceutics
Chemionization Mass Spectroscopy
University of California - School of Pharmacy
San Francisco, California 1974-1975

Survey of Nuclear Medicine
Parklawn Training Institute
Rockville, Maryland 1976

Supervisory Training
Parklawn Training Institute
Rockville, Maryland 1974

Bioavailability of Drugs and Clinical Pharmacokinetics
Center for Professional Advancement
New Jersey 1974

Workshop on Biochemical Pharmacology
University of California - School of Medicine
San Francisco, California 1973

Biopharmaceutics
University of Cincinnati
Cincinnati, Ohio 1973

Project Officer Training Course
Ohio State University/FDA Training Institute 1973

Working Statistics for Engineers, Scientists and Managers
George Washington University
School of Engineering and Applied Sciences
Washington, D. C. 1973

Bioavailability
FDA Training Institute
Rockville, Maryland 1972

Solid Dosage Forms
University of Wisconsin
Madison, Wisconsin 1972

Nuclear Chemistry
FDA Training Institute for Chemists
Rockville, Maryland 1971

Food and Drug Law Course
George Washington University Law school - Graduate Division
Washington, D. C. January - June 1969

Clinical Psychology
Army Medical Services School
Fort Sam Houston, Texas April-July 1957